INTERCEPT PHARMACEUTICALS INC
Form 10-Q
November 26, 2012

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2012

OR

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

For the transition period from to

Commission file number: 001-35668

INTERCEPT PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Its Charter)

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

(646) 747-1000

(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ¨ No x

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

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

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

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

As of November 12, 2012, there were 16,512,217 shares of common stock, $0.001 par value per share, outstanding.

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Intercept Pharmaceuticals, Inc.

(A Development Stage Company)

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FORWARD-LOOKING STATEMENTS

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

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

- our ability to obtain additional financing;
- the accuracy of our estimates regarding expenses, future revenues and capital requirements;
- the success and timing of our preclinical studies and clinical trials;
- our ability to obtain and maintain regulatory approval of obeticholic acid, or OCA, and any other product candidates we may develop, and the labeling under any approval we may obtain;
- regulatory developments in the United States and other countries;
- the performance of third-party manufacturers;
- our plans to develop and commercialize our product candidates;
- our ability to obtain and maintain intellectual property protection for our product candidates;

- the successful development of our sales and marketing capabilities;
- the potential 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; and
- the loss of key scientific or management personnel.

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

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

PART I

Item 1. FINANCIAL STATEMENTS

INTERCEPT PHARMACEUTICALS, INC.
(A Development Stage Company)
Condensed Consolidated Balance Sheets

	December 31, 2011 (Audited)	**September 30,** 2012 (Unaudited)
Assets		
Current assets:		
Cash and cash equivalents	$17,707,476	$35,971,386
Certificates of deposit	200,775	77,572
Prepaid expenses and other current assets	995,843	2,105,979
Total current assets	18,904,094	38,154,937
Fixed assets, net	311,366	157,009
Security deposits	254,869	257,673
Total assets	$19,470,329	$38,569,619
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable, accrued expenses and other liabilities	$1,504,198	$4,090,473
Short-term portion of warrant liability	—	334,438
Short-term portion of deferred revenue	2,446,107	1,621,622
Short-term portion of capital leases	81,762	—
Total current liabilities	4,032,067	6,046,533
Long-term liabilities:		
Long-term portion of deferred revenue	12,162,163	10,945,948
Long-term portion of warrant liability	5,835,877	5,939,654
Total liabilities	22,030,107	22,932,135
Stockholders' equity (deficit):		
Series A preferred stock. Authorized, issued, and outstanding 13,888,889 shares; par value $0.001 per share; liquidation preference of $1.80 per share plus accumulated dividends ($5,412,329 at December 31, 2011 and $6,537,219 at September 30, 2012)	13,889	13,889
Series B preferred stock. Authorized, issued, and outstanding 13,888,889 shares; par value $0.001 per share; liquidation preference of $1.80 per share plus accumulated dividends ($2,901,370 at December 31, 2011 and $4,026,260 at September 30, 2012)	13,889	13,889
Series C preferred stock. 0 shares authorized and outstanding as of December 31, 2011 and 25,000,000 shares authorized and 15,000,000 shares outstanding as of September 30, 2012, respectively; par value $0.001 per share; liquidation preference $2.00 per share plus accumulated dividends ($250,000 at September 30, 2012)	—	15,000
	3,330	3,330

Common stock. 65,000,000 shares and 150,000,000 shares authorized as of December 31, 2011 and September 30, 2012, respectively; 3,329,666 issued and outstanding; par value $0.001		
Additional paid-in capital	72,133,893	103,084,323
Accumulated other comprehensive loss	(184,500)	—
Accumulated deficit during development stage	(74,540,279)	(87,492,947)
Total stockholders' equity (deficit)	(2,559,778)	15,637,484
Total liabilities and stockholders' equity (deficit)	$19,470,329	$38,569,619

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 September 30,		**Nine Months Ended September 30,**		**Period from September 4, 2002 (Inception) Through September 30,**
	2011	2012	2011	2012	2012
Licensing revenue	$640,972	$523,191	$1,046,377	$2,040,700	$3,845,830
Costs and expenses:					
Research and development	2,512,248	3,318,310	7,263,061	11,395,924	66,648,051
General and administrative	1,154,090	991,062	3,174,086	2,994,121	27,415,074
Total costs and expenses	3,666,338	4,309,372	10,437,147	14,390,045	94,063,125
Other income (expense):					
Revaluation of warrants	174,338	(1,417,690)	268,543	(438,215)	1,111,807
Foreign currency loss on liquidation	—	—	—	(191,733)	(191,733)
Interest and dividend income	12,987	13,473	42,248	30,857	1,588,544
Interest expense, net	(2,889)	3,410	(11,867)	(4,232)	(273,229)
QTDP grant	—	—	—	—	488,959
	184,437	(1,400,807)	298,925	(603,323)	2,724,348
Net loss	(2,840,930)	(5,186,988)	(9,091,846)	(12,952,668)	(87,492,947)
Dividend on preferred stock, not declared	(750,000)	(1,000,000)	(2,250,000)	(2,500,000)	(10,813,479)
Net loss attributable to common stockholders	$(3,590,930)	$(6,186,988)	$(11,341,846)	$(15,452,668)	$(98,306,426)
Net loss per share, basic and diluted	$(1.08)	$(1.86)	$(3.41)	$(4.64)	
Weighted average shares outstanding, basic and diluted	3,329,666	3,329,266	3,329,666	3,329,666	
Other comprehensive loss:					
Foreign currency translation adjustments	(63,748)	—	(28,122)	184,500	—
Total comprehensive loss	$(2,904,678)	$(5,186,988)	$(9,119,968)	$(12,768,168)	$(87,492,947)

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 30,		**Period from September 4, 2002 (Inception) Through September 30,**
	2011	2012	2012
Cash flows from operating activities:			
Net loss	$(9,091,846)	$(12,952,668)	$(87,492,947)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:			
Stock-based compensation	1,178,035	1,251,579	7,680,460
Revaluation of warrants	(268,543)	438,215	(1,111,807)
Impairment of bonds	—	—	151,402
Loss from sale of assets	217,296	—	217,296
Depreciation	320,525	178,469	2,343,815
Foreign currency loss on liquidation	—	191,733	191,733
Changes in:			
Prepaid expenses and other current assets	(467,661)	(1,110,136)	(2,082,065)
Accounts payable, accrued expenses, and other current liabilities	576	2,586,275	4,090,476
Deferred revenue	15,367,024	(2,040,700)	12,567,570
Interest accrued on promissory notes	—	—	91,249
Net cash (used in) provided by operating activities	7,255,406	(11,457,233)	(63,352,818)
Cash flows from investing activities:			
Redemptions of (investments in) certificates of deposit	(14,685)	120,399	(510,560)
Purchases of equipment, improvements, and furniture and fixtures	(50,412)	(24,112)	(1,382,555)
Net cash provided by (used in) investing activities	(65, 097)	96,287	(1,893,115)
Cash flows from financing activities:			
Proceeds from issuance of common stock	—	—	21,536,300
Proceeds from issuance of preferred stock	—	30,000,000	74,801,783
Proceeds from issuance of common stock warrants	—	—	7,385,897
Costs associated with issuance of stock	—	(286,149)	(2,647,066)
Payments of capital lease obligation	(173,064)	(81,762)	(1,335,567)
Proceeds from exercise of options	—	—	42,705
Proceeds from exercise of warrants	—	—	375,000
Proceeds from issuance of convertible promissory notes payable	—	—	1,250,000
Net cash provided by (used in) financing activities	(173,064)	29,632,089	101,409,052
Effect of exchange rate changes	42,698	(7,233)	(191,733)
Net increase in cash and cash equivalents	7,059,943	18,263,910	35,971,386

Cash and cash equivalents – beginning of period	15,423,746	17,707,476	—
Cash and cash equivalents – end of period	$22,483,689	$35,971,386	$35,971,386
Supplemental disclosure of cash flow information:			
Cash paid during the year for interest	$11,867	$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

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 disease 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.

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 will receive 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.

In October 2012, the Company completed the initial public offering (IPO) of its common stock pursuant to a registration statement on Form S-1. In the IPO, the Company sold an aggregate of 5,750,000 shares of common stock under the registration statement at a public offering price of $15.00 per share. Net proceeds were approximately $78.7 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company. Upon the closing of the IPO, all outstanding shares of the Company's preferred stock 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.

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 final prospectus dated October 10, 2012 filed pursuant to Rule 424(b) under the Securities Act of 1933, as amended, with the Securities and Exchange Commission on October 11, 2012. The results for the three and nine months ended September 30, 2012 and for the period from inception (September 4, 2002) through September 30, 2012 are not necessarily indicative of results to be expected for the year ending December 31, 2012, any other interim periods or any future year or period.

2. Significant Agreements

Dainippon Sumitomo Pharma Co, Ltd. (DSP)

In March 2011, the Company entered into an exclusive license agreement with DSP to research, develop and commercialize 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 exclusive option to add several other Asian countries to its territory, including Korea and Taiwan, and to pursue OCA for additional indications. DSP will be responsible for the costs of developing and commercializing OCA in its territory.

The Company has evaluated the license agreement with DSP and has 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, 2011 and 2012, the Company recorded revenue of $405,000 (unaudited) and $405,000 (unaudited), respectively, and during the nine months ended September 30, 2011 and 2012, the Company recorded revenue of $810,000 (unaudited) and $1.2 million (unaudited), respectively, in "Licensing Revenue" in its Consolidated Statement of Operations for the Company's efforts under the agreement. The Company has not achieved any of the milestones relating to the agreement as of September 30, 2012 and has not recognized any revenue related to such milestones. The Company has determined that each potential future development, regulatory and sales milestone is substantive.

Les Laboratories Servier and Institut de Recherches Servier

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

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

Intercept and Servier will jointly support the discovery effort, while Servier alone will be responsible for all costs associated with the global development, regulatory approval and commercialization of any compound selected as a

lead candidate by the parties. The Company agreed to reimburse Servier up to a mid-double digit percentage of the total historical development costs incurred by Servier in relation to clinical development activities aimed at achieving regulatory approval in the European Union and the United States if the Company enters into a partnership agreement, or commences development or commercialization activities, with respect to any such compound in the United States. Servier may credit a portion of any reimbursable development costs against any milestone or royalty payments due and payable to the Company by Servier under the research collaboration agreement until all such reimbursable amounts are repaid. During the three and nine months ended September 30, 2011 and 2012, the Company did not reimburse any development costs to Servier nor is it expected that any such costs will be reimbursed during 2012, as no such reimbursable developments costs are planned during the period.

The Company has evaluated the research collaboration agreement with Servier and has 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, initially, the license does not have stand-alone value to Servier without the Company's technical expertise and committee participation. The research portion of the collaboration may be extended by mutual agreement by the parties for one or more additional years. In July 2012, the term of the research program was extended until January 31, 2013 on the same financial terms as the existing research program, including the reimbursement by Servier of the full time equivalent costs incurred by the Company in the conduct of the research program, up to a set maximum amount. The up-front payment is being recognized ratably over the estimated 12-month performance period as the research and development and executive committee services are being provided. During the three months ended September 30, 2011 and 2012, the Company recorded revenue of $236,000 (unaudited) and $118,000 (unaudited), respectively, and during the nine months ended September 30, 2011 and 2012, the Company recorded revenue of $236,000 (unaudited) and $824,000 (unaudited), 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 has been fully recognized as of September 30, 2012, no further revenue will be recognized. The Company has determined that each potential future development, regulatory and sales milestone is substantive.

The Company is also receiving reimbursement from Servier for research services outlined in the agreements in which the Company engaged Professor Pellicciari and TES Pharma SRL (TES) as described below. The Company is recognizing this expense reimbursement as a reduction of research and development expenses as the Company is acting as an agent regarding these research activities. All amounts incurred by the Company for research under the Servier agreement during the nine months ended September 30, 2012, including the amounts incurred under the related agreements with Professor Pellicciari and TES, were covered under the Servier agreement. At December 31, 2011 and September 30, 2012, the Company has recorded $486,000 and $321,000 (unaudited), respectively in prepaid expenses and other assets for amounts due from Servier for such expense reimbursement.

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

The Company is engaged in a sponsored research agreement with the University of Perugia and Professor Roberto Pellicciari, a founder of the Company, to design, synthesize, optimize, scale-up, and develop pharmacologically active ligands for bile acid receptors. Under the SRA, the Company is assigned ownership of any patent and intellectual property rights arising from the research project. The Company paid the University of Perugia €100,000 quarterly commencing July 1, 2006 through 2010 and €100,000 for the fiscal year 2011. In 2012, the Company amended and restated the SRA to extend the term to the end of 2012 and will pay the University of Perugia €80,000 during fiscal 2012. The Company has recognized expense for the three months ended September 30, 2011 and 2012 of $12,000 (unaudited) and $16,000 (unaudited), respectively, and for the nine months ended September 30, 2011 and 2012 of $82,000 (unaudited) and $77,000 (unaudited), respectively.

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. On January 1, 2011, the Company entered into an amended and restated consulting and intellectual property agreement with Professor Pellicciari, pursuant to which the Company agreed to pay Professor Pellicciari an aggregate of €100,000 for services to be provided through December 31, 2011 for consulting services and intellectual property rights in relation to OCA, INT-767 and INT-777 product candidates. This agreement has been extended through December 31, 2012 and the Company has agreed to pay Professor Pellicciari an aggregate of €100,000 for consulting services and intellectual property rights through the end of this period.

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

provides 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 has been agreed upon by the parties as of September 30, 2012. In July 2012, by mutual agreement of the parties, the term of this agreement was extended until January 31, 2013 in conjunction with the extension of the term of the research program with Servier on the same financial terms as the original consulting agreement with Professor Pellicciari.

The Company has recognized expense related to these agreements for the three months ended September 30, 2011 and 2012 of $69,000 (unaudited) and $80,000 (unaudited), respectively, and for the nine months ended September 30, 2011 and 2012 of $139,000 (unaudited) and $243,000 (unaudited), respectively.

TES Pharma SRL

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

The Company has incurred charges related to this agreement for the three months ended September 30, 2011 and 2012 of $243,000 (unaudited) and $310,000 (unaudited), respectively, and for the nine months ended September 30, 2011 and 2012 of $243,000 (unaudited) and $982,000 (unaudited), 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 is required to make an additional $1.25 million payment within 60 days of full enrollment of the FLINT trial, which occurred on November 12, 2012. The Company has recognized expense related to this contract for the three months ended September 30,

2011 and 2012 of $82,000 (unaudited) and $168,000 (unaudited), respectively, and for the nine months ended September 30, 2011 and 2012 of $250,000 (unaudited) and $2.2 million (unaudited), respectively.

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, 2013, which 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 has 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 has 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 an aggregate of $4.0 million under this agreement. The Company has recognized expense related to these contracts and other work orders for the three months ended September 30, 2011 and 2012 of $49,000 (unaudited) and $345,000 (unaudited), respectively, and for the nine months ended September 30, 2011 and 2012 of $273,000 (unaudited) and $1.2 million (unaudited), respectively.

3. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	December 31, 2011	**September 30,** 2012
	(In thousands)	
	(Audited)	(Unaudited)
Deferred financing costs(1)	$—	$ 1,147
Prepaid expenses	359	585
Accounts receivable	486	321
Refundable tax credits	151	52
Prepaid expenses and other current assets	$996	$ 2,105

(1)

The Company capitalized certain legal, accounting and other fees that were directly associated with the IPO. Due to the completion of the IPO in October 2012, these costs, net of proceeds received in subsequent reporting periods, will be recorded in equity.

4. Fixed Assets, Net

Fixed assets, net consisted of the following:

	December 31, 2011	September 30, 2012
	(In thousands)	
	(Audited)	(Unaudited)
Office equipment	$318	$ 343
Leasehold improvements	178	178
Furniture and fixtures under capitalized lease	157	157
Furniture and fixtures	120	121
Laboratory equipment	1,046	—
Subtotal fixed assets	1,820	799
Less: accumulated depreciation and amortization	(1,508)	(642)
Fixed assets, net	$311	$ 157

Depreciation and amortization expense for the three months ended September 30, 2011 and 2012 was $160,000 (unaudited) and $24,000 (unaudited), respectively. Depreciation and amortization expense for the nine months ended September 30, 2011 and 2012 was $321,000 (unaudited) and $178,000 (unaudited), respectively. During 2011, the Company closed its facility in Italy and in August 2011, in connection with entering into the TES agreement, transferred its rights in certain of its fixed assets located at the Italian facility to TES. As a result, the Company recognized a $217,000 loss on the disposal of fixed assets in the three and nine months ended September 30, 2011.

5. Accounts Payable, Accrued Expenses and Other Liabilities

Accrued expenses and other liabilities consisted of the following:

	December 31, 2011	September 30, 2012
	(In thousands)	
	(Audited)	(Unaudited)
NIDDK contract accrual	$—	$ 1,150
Accounts payable	604	1,048
Accrued employee compensation	728	712
Accrued site payments for clinical trials	123	485
Accrued other	49	695
Accounts payable, accrued expenses and other liabilities	$1,504	$ 4,090

6. Income Taxes

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

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

The deferred tax asset or liability represents future tax return consequences of those differences, which will be taxable when the assets and liabilities are recovered or settled. The provision for income taxes may differ from the actual expense that would result from applying the federal statutory rate to income before taxes because certain expenses for financial reporting purposes are not deductible for tax purposes. At December 31, 2011 and September 30, 2012, the Company had available net operating loss carryforwards to reduce future taxable income of approximately $55.0 million and $68.5 million (unaudited), respectively, for tax reporting purposes. As of September 30, 2012, 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 $32.1 million, and $36.5 million (unaudited) at December 31, 2011 and September 30, 2012, 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. Management has determined it is uncertain whether any of the deferred tax assets will be realizable, 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.

7. 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. 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 using the Black-Scholes option pricing model. Furthermore, certain warrants that do not have these provisions, and are currently classified in equity, contain provisions that require them to be registered upon an initial public offering. Due to the completion of the Company's IPO, these warrants will be reclassified as liabilities and warrant revaluation income (expense) will be recorded in the statements of operations in subsequent reporting periods. For the warrants classified as liabilities, the Company estimates the fair values of the warrants at each reporting period using a Black-Scholes option-pricing model. Management has 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, 2012, the Company had outstanding warrants to purchase a total of 1,232,767 shares of its common stock, at a weighted average exercise price of $9.38 per share. Of these warrants, 108,169 expire in May 2013; 239,608 expire in October 2013;19,609 expire in May 2014; and 865,381 expire in January 2015.

8. Fair Value Measurements

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

- Unadjusted Quoted Prices — The fair value of an asset or liability is based on unadjusted quoted prices in active markets for identical assets or liabilities (Level 1).
- Pricing Models with Significant Observable Inputs — The fair value of an asset or liability is based on information derived from either an active market quoted price, which may require further adjustment based on the attributes of the financial asset or liability being measured, or an inactive market transaction (Level 2).
- Pricing Models with Significant Unobservable Inputs — The fair value of an asset or liability is primarily based on internally derived assumptions surrounding the timing and amount of expected cash flows for the financial instrument. Therefore, these assumptions are unobservable in either an active or inactive market (Level 3).

	Total	Fair Value Measurements Using		
		Quoted Prices in Active Markets for Identical Assets or Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
	(In thousands)			
Description				
December 31, 2011 (audited)				
Liabilities:				
Warrants to purchase common stock	$(5,836)	$—	$ —	$ (5,836)
Total liabilities	$(5,836)	$—	$ —	$ (5,836)
September 30, 2012 (unaudited)				
Liabilities:				
Warrants to purchase common stock	$(6,274)	$—	$ —	$ (6,274)
Total liabilities	$(6,274)	$—	$ —	$ (6,274)

9. Stockholders' Equity and Preferred Stock

Common Stock

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

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

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

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

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

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

In May 2006, pursuant to a private placement agreement, the Company issued 2,087,091 shares of common stock at a price of $9.82, receiving net proceeds of $19.5 million, after $1.0 million in related offering costs. Also in May 2006, the Company's 6% convertible promissory notes that were issued in February 2005 with a face amount of $1.3 million, along with $91,000 of accrued interest, were converted into 160,649 shares of common stock at a price of $8.35 per share pursuant to the mandatory conversion terms of the notes.

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 for net proceeds of $24.0 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.

On August 9, 2012, the Company entered into a securities purchase agreement with an affiliated fund of OrbiMed Advisors LLC and Genextra, pursuant to which the Company agreed to issue up to an aggregate of 25,000,000 shares of Series C preferred stock at a price of $2.00 per share for gross proceeds of up to $50.0 million, or Series C financing. The securities purchase agreement for the Series C financing provided for the issuance of the Series C preferred stock in two tranches, consisting of 15,000,000 and 10,000,000 shares. On August 8, 2012, the Company amended and restated its Certificate of Incorporation in its entirety to increase the number of shares of preferred stock it is authorized to issue to 52,777,778 shares and designate 25,000,000 of such shares as Series C preferred stock. On August 9, 2012, the Company issued the first tranche of Series C preferred stock, which resulted in net proceeds of $29.7 million. The closing of the second tranche was only contemplated to occur if the Company did not complete an initial public offering of common stock on or prior to August 2013.

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 the agreement to issue the second tranche of Series C preferred stock was nullified.

10. Stock Based Compensation

In 2003, the Board of Directors and the stockholders of the Company approved the 2003 Plan which provided for the granting of equity awards to officers, directors, employees, advisors, and consultants of the Company. 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 Plan, which became effective upon the pricing of the Company's IPO in October 2012. The 2012 Plan will expire on September 13, 2022. Under the 2012 Plan, the Company may grant incentive stock options, non-qualified stock options, restricted and unrestricted stock awards and other stock-based awards. As of September 30, 2012, there were 728,920 shares of our common stock authorized for issuance under the 2012 Plan (including the 555,843 shares of common stock that were added from the 2003 Plan, plus such additional shares as are forfeited or canceled under the 2003 Plan).

As of September 30, 2012, options to purchase 1,322,108 shares were outstanding under the 2003 Plan. On November 16, 2012 and November 18, 2012, the Company granted to employees and directors (i) options to purchase 218,754 shares of common stock and (ii) restricted stock units for 176,188 shares of common stock, in each case, under the 2012 Plan. The Company filed a registration statement on November 7, 2012 to register the number of shares issuable upon outstanding awards and available for issuance under the 2003 Plan and 2012 Plan.

The following table summarizes stock option activity during the nine months ended September 30, 2012:

	Number of Shares	Weighted Average Exercise Price
Outstanding, December 31, 2011	1,309,364	$ 8.98
Granted	23,794	9.30
Exercised	—	—
Forfeited	(11,050)	9.13
Outstanding, September 30, 2012	1,322,108	$ 8.98
Exercisable, September 30, 2012	1,033,060	$ 9.04

11. Net Loss Per Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2012	2011	2012
	(In thousands, except share and per share amounts) (Unaudited)			
Historical net loss per share				
Numerator:				
Net loss attributable to common stockholders	$(3,591)	$(6,187)	$(11,342)	$(15,453)
Denominator:				
Weighted average shares outstanding, basic and diluted	3,329,666	3,329,666	3,329,666	3,329,666
Net loss per share, basic and diluted	$(1.07)	$(1.86)	$(3.41)	$(4.64)

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

	As of September 30,	
	2011	2012
	(Unaudited)	
Shares issuable upon conversion of preferred stock	4,808,020	7,403,817
Shares issuable pursuant to accumulated preferred stock dividend	727,276	1,037,371
Options	1,088,346	1,322,108
Warrants to purchase common stock	1,232,767	1,232,767
Total	7,856,409	10,996,063

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, 2011 included in our prospectus dated October 10, 2012 filed pursuant to Rule 424(b) under the Securities Act of 1933, as amended, or the Securities Act, with the Securities and Exchange Commission on October 11, 2012. This discussion contains forward-looking statements that involve significant risks and uncertainties. As a result of many factors, such as those set forth in Part II, Item 1.A. Risk Factors of this Quarterly Report on Form 10-Q, 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 disease 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, 2012, we have funded our operations primarily through the private placement of preferred stock, common stock, convertible notes and warrants to purchase common stock totaling $105.4 million and through the receipt of $16.4 million of up-front payments under our collaborative agreements.

In October 2012, we completed the initial public offering of our common stock, or 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 estimated offering expenses payable by us. Upon the closing of the IPO, all outstanding shares of our preferred stock were converted into 7,403,817 shares of common stock.

We have incurred net losses in each year since our inception in 2002. Our net losses were approximately $9.1 million and $12.9 million for the nine months ended September 30, 2011 and 2012, respectively. As of September 30, 2012, we had an accumulated deficit of approximately $87.4 million. Substantially all our net losses resulted from costs incurred in connection with our research and development programs and from general and administrative costs

associated with our operations.

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

- complete the development of our lead product candidate, obeticholic acid, or OCA, for the treatment of primary biliary cirrhosis, or PBC;
- seek to obtain regulatory approvals for OCA;
- outsource the commercial manufacturing of OCA for any indications for which we receive regulatory approval;
- contract with third parties for the sales, marketing and distribution of OCA for any indications for which we 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 in addition to the net proceeds of our initial public offering completed in October 2012 as described above, 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. We are currently in the process of liquidating this subsidiary. However, we are continuing our early stage TGR5 research through our collaboration with Les Laboratories Servier and Institut de Recherches Servier, or collectively Servier. Although our Italian subsidiary is currently in liquidation and essentially inactive, we do not intend to liquidate this subsidiary for some time because it acts as our legal representative for our clinical trials in the European Union to satisfy European Union regulatory requirements.

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 Dainippon Sumitomo Pharma Co. Ltd., or 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 $138.8 million as of September 30, 2012) 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 the nine months ended September 30, 2012, we recognized $2.0 million in license revenue for the relevant amortization of the two up-front payments. We expect to recognize as revenue an additional $400,000 for the amortization of these payments through 2012 and do not expect to receive any milestone payments during 2012 related to these agreements. As the Servier up-front payment has been fully recognized as of September 30, 2012, no further revenue will be recognized. 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.

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, 2012, we have incurred approximately $66.6 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 “Indirect research and development expense” in the table below.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2012	2011	2012
	(In thousands) (Unaudited)			
Direct research and development expense	$1,691	$2,187	$5,036	$8,122
Personnel costs	742	933	1,922	2,763
Indirect research and development expense	79	198	305	511
Total research and development expense	$2,512	$3,318	$7,263	$11,396

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 enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

OCA

The majority of our research and development resources are focused on our Phase 3 clinical trial in patients with PBC, or POISE trial, and our other planned clinical and preclinical 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, and as of September 30, 2012, we had enrolled approximately two-thirds of the total number of patients targeted for our POISE trial. We currently expect results from the trial to be available by mid-2014. Patients who complete twelve months of treatment will be eligible to continue in an open label safety extension trial for five years.

- We are continuing to treat PBC patients from our Phase 2 trial with OCA in a long-term safety extension trial. As of September 30, 2012, there were 27 patients being followed in this trial and we anticipate the trial to continue through 2014.

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

- We plan to initiate a Phase 1 clinical trial in healthy volunteers to evaluate the effect of OCA on the heart's electrical cycle, known as the QT interval, and additional Phase 1 clinical trials in 2013.

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

In addition, we are evaluating OCA in other chronic liver and other diseases. In connection with these efforts, we have incurred and expect to incur 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 is required to be paid within 60 days of full enrollment of the FLINT trial, which occurred on November 12, 2012.

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 and INT-777 directly or 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. Other significant general and administrative expenses include allocation of facilities costs, professional fees for directors, accounting and legal services and expenses associated with obtaining and maintaining patents.

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

Interest and Dividend Income (Expense), Net

Interest income consists of interest earned on our cash and cash equivalents. We expect our interest income to increase as we invest the net proceeds from the IPO.

Interest expense pertains to equipment currently under a capitalized lease. This capitalized lease matured in 2012 and, as such, we will no longer be subject to the interest expense under this capitalized lease.

Revaluation of Warrants

In conjunction with various financing transactions, we issued warrants to purchase shares of our common stock. Certain of the warrants include a provision that provides for a reduction in the warrant exercise price if there are subsequent issuances of additional shares of common stock for consideration per share less than the applicable per share warrant exercise price. The warrants containing this provision are deemed to be derivative instruments and as such, are recorded as a liability and marked-to-market at each reporting period using a Black-Scholes option-pricing model. Certain warrants that do not have these down-round provisions, and were classified in equity, as of September 30, 2012, contain provisions that may require the shares of common stock underlying them to be registered upon an initial public offering. Due to the completion of our IPO, these warrants will be reclassified as liabilities and warrant revaluation income (expense) will be recorded in the statement of operations in subsequent reporting periods. The fair value estimates of these warrants 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. Now that the Company is a public company, these fluctuations are expected to increase or decrease significantly based on changes in the price of the Company's common stock.

Results of Operations

Comparison of the Three Months Ended September 30, 2011 and the Three Months Ended September 30, 2012

The following table summarizes our results of operations for each of the three months ended September 30, 2011 and 2012, together with the changes in those items in dollars and as a percentage:

	Three Months Ended September 30,		Dollar Change	% Change
	2011	2012		
	(In thousands)			
	(Unaudited)			
Licensing revenue	$641	$523	$(118)	(18.4%)
Costs and expenses:				
Research and development	2,512	3,318	806	32.1%
General and administrative	1,154	991	(163)	(14.1%)
Total costs and expenses	3,666	4,309	643	17.5%
Other income (expense):				
Revaluation of warrants	174	(1,418)	(1,592)	*
Interest and dividend income and expense, net	10	17	7	*
Net loss	$(2,841)	$(5,187)	$(2,346)	82.6%

*Not meaningful or not calculable.

Licensing Revenue

Licensing revenue was $641,000 and $523,000 for the three months ended September 30, 2011 and 2012, respectively, resulting from the amortization of the up-front payments from the collaboration agreements entered into with DSP on March 29, 2011 and with Servier on August 1, 2011.

Research and Development Expenses

Research and development expenses were $2.5 million and $3.3 million for the three months ended September 30, 2011 and 2012, respectively, representing an increase of $806,000, or 32.1%. This increase in research and development expense primarily reflects:

- increased direct development expense for our Phase 3 POISE trial of approximately $927,000;
- an increase in personnel on our development team to manage the increased activities around our development program for OCA, resulting in increased compensation expense of approximately $191,000 and associated overhead of approximately $79,000;
- increased direct development expense for our two-year animal carcinogenicity studies in two species of approximately $122,000; and
- a partial offset by decreases in costs related to (i) research expenses for our earlier stage pipeline assets of $160,000; (ii) decreased costs to manufacture our clinical trial supplies of $153,000; (iii) decreased costs associated with regulatory consultants of $100,000; and (iv) decreased costs associated with market research of $105,000.

General and Administrative Expenses

General and administrative expenses were $1.1 million and $1.0 million in the three months ended September 30, 2011 and 2012, respectively. The $163,000 decrease was primarily related to additional legal costs associated with the Servier collaboration agreement and higher patent costs incurred in the three months ended September 30, 2011.

Revaluation of Warrants

Some of our outstanding warrants are deemed to be derivative instruments that require liability classification and mark-to-market accounting. As such, at the end of each reporting period, the fair values of the warrants were

determined by us using a Black-Scholes option-pricing model, resulting in the recognition of a gain of $174,000 and a loss of $1.4 million for the three months ended September 30, 2011 and 2012, respectively. These fluctuations in value were primarily due to the declines in the estimated life of the warrants and changes in volatility of the shares of common stock underlying the warrants. For the three months ended September 30, 2012, the fair value was also affected by the increase in the price of the common stock underlying the warrants. Now that we are a public company, these fluctuations are expected to increase or decrease significantly based on changes in the price of our common stock.

Comparison of the Nine Months Ended September 30, 2011 and the Nine Months Ended September 30, 2012

The following table summarizes our results of operations for each of the nine months ended September 30, 2011 and 2012, together with the changes in those items in dollars and as a percentage:

	Nine Months Ended September 30,		Dollar Change	% Change
	2011	2012		
	(In thousands)			
	(Unaudited)			
Licensing revenue	$1,046	$2,041	$995	95.0 %
Costs and expenses:				
Research and development	7,263	11,396	4,133	56.9 %
General and administrative	3,174	2,994	(180)	(5.7 %)
Total costs and expenses	10,437	14,390	3,953	37.9 %
Other income (expense):				
Revaluation of warrants	269	(438)	(707)	*
Foreign currency loss in liquidation	—	(192)	(192)	*
Interest and dividend income and expense, net	30	27	(3)	(12.4 %)
Net loss	$(9,092)	$(12,952)	$(3,860)	42.4 %

*Not meaningful or not calculable.

Licensing Revenue

Licensing revenue was $1.0 million and $2.0 million for the nine months ended September 30, 2011 and 2012, respectively, resulting from the amortization of the up-front payments from the collaboration agreements entered into with DSP on March 29, 2011 and with Servier on August 1, 2011.

Research and Development Expenses

Research and development expenses were $7.3 million and $11.4 million for the nine months ended September 30, 2011 and 2012, respectively. The increase in research and development expenses of $4.1 million, or 56.9%, was primarily due to:

- increased direct development expense for our Phase 3 POISE trial of approximately $2.4 million;
- increased expenses of $1.7 million payable by us to the NIDDK relating to milestones achieved and expected to be achieved under the NIDDK agreement;
- an increase in personnel on our development team to manage the increased activities around our development program for OCA, resulting in increased compensation expense of approximately $841,000 and associated overhead of $205,000;
- increased direct development expense for our two-year animal carcinogenicity studies in two species of approximately $822,000;
- increased direct development expense for the Phase 2 clinical trial for portal hypertension of approximately $137,000;
- reduced direct research and development expense of approximately $1.0 million resulting from the closure of our research facility in June 2011 and research associated with our TGR5 program, which was previously paid by us and is now funded through our collaboration with Servier;
- reduced direct research and development expense with respect to the completion of our Phase 2 trials for OCA of approximately $270,000;
- reduced direct research and development expense relating to INT-777 of approximately $140,000;
- decreased costs to manufacture our clinical trial supplies of approximately $214,000;
- decreased costs associated with regulatory consultants of $95,000 and
- decreased costs associated with market research of $105,000.

General and Administrative Expenses

General and administrative expenses were $3.2 million and $3.0 million for the nine months ended September 30, 2011 and 2012, respectively. The decrease in general and administrative expenses of $180,000, or 5.7%, was mainly primarily due to legal costs associated with the DSP and Servier collaboration agreements of $150,000 incurred 2011,

but not in 2012.

Revaluation of Warrants

Some of our outstanding warrants are deemed to be derivative instruments that require liability classification and mark-to-market accounting. At the end of each reporting period, the fair values of the warrants were determined using a Black-Scholes option-pricing model, resulting in the recognition of a gain of $268,000 and loss of $438,000 for the nine months ended September 30, 2011 and 2012, respectively. These fluctuations were primarily due to the reduction in value of the warrants as their estimated life declines and changes in volatility of the shares of common stock underlying the warrants. For the nine months ended September 30, 2012, the fair value was also affected by the increase in the price of the common stock underlying the warrants. Now that we are a public company, 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, 2012, we had an accumulated deficit of $87.4 million. We anticipate that we will continue to incur losses for at least the next several years. We expect that our research and development and general and administrative expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may seek to obtain through a combination of equity offerings, debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements.

Since our inception through September 30, 2012, we have funded our operations principally with $102.7 million (net of issuance costs of $2.7 million) from the sale of common stock, preferred stock, convertible notes and warrants, 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, 2012, we had cash and cash equivalents of approximately $36.0 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation and as of September 30, 2012, our funds were held in cash and money market bank accounts.

On August 9, 2012, we entered into a securities purchase agreement with an affiliated fund of OrbiMed Advisors LLC and Genextra S.p.A., or Genextra, pursuant to which the we agreed to issue up to an aggregate of 25,000,000 shares of Series C preferred stock at a price of $2.00 per share for gross proceeds of up to $50.0 million, or the Series C financing. The securities purchase agreement for the Series C financing provided for the issuance of the Series C preferred stock in two tranches, consisting of 15,000,000 and 10,000,000 shares. On August 8, 2012, we amended and restated our Certificate of Incorporation in its entirety to increase the number of shares of preferred stock we are authorized to issue to 52,777,778 shares and designate 25,000,000 of such shares as Series C preferred stock. On August 9, 2012, we issued the first tranche of Series C preferred stock, which resulted in net proceeds of $29.7 million to us. The closing of the second tranche was only contemplated to occur if we did not complete an initial public offering of our common stock on or prior to August 2013.

Upon the completion of the IPO, all outstanding shares of our preferred stock were converted into 7,403,817 shares of common stock and the agreement to issue the second tranche of Series C preferred stock was nullified.

In October 2012, we completed our 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 estimated 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.

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,	
	2011	2012
	(In thousands)	
	(Unaudited)	
Net cash provided by (used in):		
Operating activities	$7,255	$(11,457)
Investing activities	(65)	96
Financing activities	(173)	29,632
Effect of exchange rate changes	43	(7)
Net increase in cash	$7,060	$18,264

Operating Activities. Net cash provided by operating activities of $7.3 million during the nine months ended September 30, 2011 was primarily a result of our $9.1 million net loss, offset by the $15.4 million of deferred revenue from the upfront payment under our collaborations with DSP and Servier, and the add-back of non-cash expenses of $1.2 million for stock-based compensation and $320,000 for depreciation and $268,000 for warrant liability revaluation. Net cash used in operating activities of $11.5 million during the nine months ended September 30, 2012 was primarily a result of our $12.9 million net loss, offset by the add-back of non-cash expenses of $1.3 million for stock-based compensation and $178,000 for depreciation and $438,000 for warrant liability revaluation.

Financing Activities. Net cash used in financing activities during the nine months ended September 30, 2011 consisted of payments under capital lease obligations. Net cash provided by financing activities in the nine months ended September 30, 2012 consisted primarily of approximately $29.6 million in net proceeds from the sale of Series C preferred stock.

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 also expect to incur additional costs associated with operating as a public company. In addition, subject to obtaining regulatory approval of any of our product candidates, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. We anticipate that we will need substantial additional funding in connection with our continuing operations.

We believe that the net proceeds from our IPO completed in October 2012, together with our existing cash, cash equivalents, short-term investments and anticipated funding under our DSP and Servier collaborations, will enable us to fund our operating expenses and capital expenditure requirements through 2016. We have based our estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures necessary to complete the development of our product candidates.

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

- the progress, costs, results and timing of our POISE trial, and the clinical development of OCA for other potential indications;
- the willingness of the FDA and the European Medicines Agency, or EMA, to accept our POISE trial, as well as our other completed and planned clinical and preclinical studies and other work, as the basis for review and approval of OCA for PBC;
- the outcome, costs and timing of seeking and obtaining FDA, EMA and any other regulatory approvals;
- the number and characteristics of product candidates that we pursue, including our product candidates in preclinical development;
- the ability of our product candidates to progress through clinical development successfully;
- our need to expand our research and development activities;
- the costs associated with securing and establishing commercialization and manufacturing capabilities;
- the costs of acquiring, licensing or investing in businesses, products, product candidates and technologies;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- our need and ability to hire additional management and scientific and medical personnel;
- the effect of competing technological and market developments;
- our need to implement additional internal systems and infrastructure, including financial and reporting 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

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 final prospectus dated October 10, 2012 filed pursuant to Rule 424(b) of the Securities Act with the Securities and Exchange Commission on October 11, 2012.

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 final prospectus dated October 10, 2012 filed pursuant to Rule 424(b) of the Securities Act with the Securities and Exchange Commission on October 11, 2012.

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, 2012, have concluded that, based on such evaluation, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms of the Securities and Exchange Commission, and is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(d) and 15d-15(d) under the Exchange Act) occurred during the three months ended September 30, 2012 that has materially affected, or is 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 material legal proceedings.

Item 1A. Risk Factors.

Risks Relating to Our Financial Position and Need for Additional Capital

We have never been profitable. Currently, we have no products approved for commercial sale, and to date we have not generated any revenue from product sales. As a result, our ability to reduce our losses and reach profitability is unproven, and we may never achieve or sustain profitability.

We have never been profitable and do not expect to be profitable in the foreseeable future. We have not yet submitted any product candidates for approval by regulatory authorities in the United States or elsewhere for our lead indication, primary biliary cirrhosis, or PBC, or any other indication. We have incurred net losses in each year since our inception and had an accumulated deficit of $87.4 million as of September 30, 2012. Our working capital and cash and cash equivalents as of September 30, 2012 were $32.1 million and $36.0 million, respectively. In addition, in October 2012, we completed the initial public offering of our common stock, or IPO, and received net proceeds of approximately $78.7 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

To date, we have devoted most of our financial resources to our corporate overhead and research and development, including our drug discovery research, preclinical development activities and clinical trials. We have not generated any revenues from product sales. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, obeticholic acid, or OCA, which is our lead product candidate, and our other product candidates, prepare for and begin the commercialization of any approved products, and add infrastructure and personnel to support our product development efforts and operations as a public company. We anticipate that any such losses could be significant for the next several years as we complete our Phase 3 clinical trial of OCA in PBC, which we call the POISE trial, and related activities required for regulatory approval of OCA and continue pursuing additional indications for OCA in clinical trials. If OCA or any of our other product candidates fails in clinical trials or does not gain regulatory approval, or if our product candidates do not achieve market acceptance, we may never become profitable. As a result of the foregoing, we expect to continue to experience net losses and negative cash flows for the foreseeable future. These net losses and negative

cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. In addition, our expenses could increase if we are required by the U.S. Food and Drug Administration, or FDA, or the European Medicines Agency, or EMA, to perform studies or trials in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our product candidates. The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues.

We will require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not so available, may require us to delay, limit, reduce or cease our operations.

We are currently advancing OCA through clinical development for multiple indications and other product candidates through preclinical development. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We will require substantial additional future capital in order to complete clinical development and commercialize OCA, and to conduct the research and development and clinical and regulatory activities necessary to bring other product candidates to market. For instance, to complete the work necessary to file a New Drug Application, or NDA, and a Marketing Authorization Application, or MAA, for OCA as a treatment for PBC, which is currently anticipated to occur in 2014, we estimate that our ongoing Phase 3 POISE trial, and our planned clinical and preclinical studies, as well as other work needed to submit OCA for the treatment of PBC for regulatory approval in the United States, Europe and other countries, will cost approximately $40.0 million, including the internal resources needed to manage the program. If the FDA or EMA requires that we perform additional preclinical studies or clinical trials, our expenses would further increase beyond what we currently expect and the anticipated timing of any potential NDA or MAA would likely be delayed.

The net proceeds received upon the completion of our IPO in October 2012, combined with our existing cash and cash equivalents, will not be sufficient to complete advanced clinical development of any of our product candidates other than OCA for PBC. Accordingly, we will continue to require substantial additional capital to continue our clinical development and commercialization activities. Because successful development of our product candidates is uncertain, we are unable to estimate the actual funds we will require to complete research and development and commercialize our products under development.

The amount and timing of our future funding requirements will depend on many factors, including but not limited to:

- the progress, costs, results of and timing of our Phase 3 POISE trial of OCA for the treatment of PBC, and the clinical development of OCA for other potential indications;
- the willingness of the FDA and EMA to accept our POISE trial, as well as our other completed and planned clinical and preclinical studies and other work, as the basis for review and approval of OCA for PBC;
- the outcome, costs and timing of seeking and obtaining FDA, EMA and any other regulatory approvals;
- the number and characteristics of product candidates that we pursue, including our product candidates in preclinical development, such as INT-777 and INT-767;
- 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;
- market acceptance of our product candidates;
- the costs of acquiring, licensing or investing in businesses, products, product candidates and technologies;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- our need and ability to hire additional management and scientific and medical personnel;
- the effect of competing technological and market developments;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems; and
- the economic and other terms, timing of and success of our existing licensing arrangements and any collaboration, licensing or other arrangements into which we may enter in the future.

Some of these factors are outside of our control. Based upon our currently expected level of operating expenditures, we believe that we will be able to fund our operations through 2016. This period could be shortened if there are any significant increases in planned spending on development programs or more rapid progress of development programs than anticipated. We do not expect our existing capital resources to be sufficient to enable us to complete the commercialization of OCA, if approved, or to initiate all the clinical trials or additional development work needed for any of our other product candidates. Accordingly, we expect that we will need to raise additional funds in the future.

We may seek additional funding 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. Additional funding may not be available to us on acceptable terms or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. In addition, the issuance of additional shares by us, or the possibility of such issuance, may cause the market price of our shares to decline.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail one or more of our research or development programs. We also could be required to seek funds through arrangements with collaborative partners or otherwise that may require us to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us.

Our revenues to date have been generated through our collaboration agreements and we may not receive any additional revenues under such agreements.

To date, our sources of revenue have been the up-front payments received under our collaboration and license agreements with Dainippon Sumitomo Pharma Co. Ltd., or DSP, and Les Laboratoires Servier and Institut de Recherches Servier, which are collectively referred to as Servier. Additional payments under each of the DSP and Servier agreements are based on the achievement of various research, development, regulatory and commercial sales milestones and royalty payments based on the sales of the products covered by such agreements. Future payments from DSP and Servier under their respective collaboration and license agreements are uncertain because DSP or Servier, as the case may be, may choose not to continue research or development of activities for the product candidates under license in their licensed territory, the product candidates may not be approved for the proposed indications or, even if any product candidate is approved for one or more indications, it may not be commercially successful. If we are unable to develop and commercialize one or more of our product candidates, either alone or with collaborators, or if revenues from any such collaboration product candidate that receives marketing approval are insufficient, we will not achieve profitability. Even if we achieve profitability, we may not be able to sustain or increase profitability.

We have a limited operating history and we expect a number of factors to cause our operating results to fluctuate on a quarterly and annual basis, which may make it difficult to predict our future performance.

We are a development stage biopharmaceutical company with a limited operating history. Our operations to date have been limited to developing our technology and undertaking preclinical studies and clinical trials of our product candidates. We have not yet obtained regulatory approvals for any of our product candidates. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history or approved products on the market. Our financial condition and operating results have varied significantly in the past and are expected to continue to significantly fluctuate from quarter-to-quarter or year-to-year due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include:

- any delays in regulatory review and approval of our product candidates in clinical development, including our ability to receive approval from the FDA and the EMA for OCA for the treatment of PBC based on our Phase 3 POISE trial, and our other completed and planned clinical and preclinical studies and other work, as the basis for review and approval of OCA for PBC;
- delays in the commencement, enrollment and timing of clinical trials;
- difficulties in identifying and treating patients suffering from our target indications, and PBC in particular, which is considered to be a rare disease;
- the success of our clinical trials through all phases of clinical development, including our POISE trial of OCA for the treatment of PBC;
- potential side effects of our product candidates that could delay or prevent approval or cause an approved drug to be taken off the market;
- our ability to obtain additional funding to develop our product candidates;
- our ability to identify and develop additional product candidates;
- market acceptance of our product candidates;
- our ability to establish an effective sales and marketing infrastructure directly or through collaborations with third parties;

- competition from existing products or new products that may emerge;
- the ability of patients or healthcare providers to obtain coverage or sufficient reimbursement for our products;
- our ability to adhere to clinical study requirements directly or with third parties such as contract research organizations, or CROs;
- our dependency on third-party manufacturers to manufacture our products and key ingredients;
- our ability to establish or maintain collaborations, licensing or other arrangements;
- the costs to us, and our ability and our third-party collaborators' ability to obtain, maintain and protect our intellectual property rights;
- costs related to and outcomes of potential intellectual property litigation;
- our ability to adequately support future growth;
- our ability to attract and retain key personnel to manage our business effectively;
- our ability to build our finance infrastructure and improve our accounting systems and controls;
- potential product liability claims;
- potential liabilities associated with hazardous materials; and
- our ability to obtain and maintain adequate insurance coverage.

In addition, our financial results may vary due to fluctuations in our warrant liability. Accordingly, our financial results for any period should not be relied upon as indications of future operating performance.

Our recurring losses from operations may raise substantial doubt regarding our ability to continue as a going concern.

Our recurring losses from operations may raise substantial doubt about our ability to continue as a going concern. If in the future, our independent registered public accounting firm were to include an explanatory paragraph in its report on our consolidated financial statements stating there is substantial doubt about our ability to continue as a going concern, such an opinion could materially limit our ability to raise additional funds through the issuance of new debt or equity securities or otherwise. There is no assurance that sufficient financing will be available when needed to allow us to continue as a going concern. The perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations.

Risks Relating to Regulatory Review and Approval of Our Product Candidates

We cannot be certain that OCA or any of our other product candidates will receive regulatory approval, and without regulatory approval we will not be able to market our product candidates.

We are initially developing OCA for the treatment of patients with PBC, portal hypertension, nonalcoholic steatohepatitis, or NASH, and bile acid diarrhea, and are also consulting with investigators to develop protocols for other indications. Our business currently depends entirely on the successful development and commercialization of OCA. Our ability to generate revenue related to product sales, if ever, will depend on the successful development and regulatory approval of OCA for the treatment of PBC and other indications and our other product candidates.

We currently have no products approved for sale and we cannot guarantee that we will ever have marketable products. The development of a product candidate and issues relating to its approval and marketing are subject to extensive regulation by the FDA in the United States, the EMA in Europe and regulatory authorities in other countries, with regulations differing from country to country. We are not permitted to market our product candidates in the United States or Europe until we receive approval of a NDA from the FDA or a MAA from the EMA, respectively. We have not submitted any marketing applications for any of our product candidates.

NDAs and MAAs must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each desired indication. NDAs and MAAs must also include significant information regarding the chemistry, manufacturing and controls for the product. Obtaining approval of a NDA or a MAA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval. The FDA and the EMA review processes can take years to complete and approval is never guaranteed. If we submit a NDA to the FDA, the FDA must decide whether to accept or reject the submission for filing. We cannot be certain that any submissions will be accepted for filing and review by the FDA. Regulators of other jurisdictions, such as the EMA, have their own procedures for approval of product candidates. Even if a product is approved, the FDA or the EMA, as the case may be, may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming clinical trials or reporting as conditions of approval. Regulatory authorities in countries outside of the United States and Europe also have requirements for approval of drug candidates with which we must comply prior to marketing in those countries. Obtaining regulatory approval for marketing of a product candidate in one country does not ensure that we will be able to obtain regulatory approval in any other country. In addition, delays in approvals or rejections of marketing applications in the United States, Europe or other countries may be based upon many factors, including regulatory requests for additional analyses, reports, data, preclinical studies and clinical trials, regulatory questions regarding different interpretations of data and results, changes in regulatory policy during the period of product development and the emergence of new information regarding our product candidates or other products. Also, regulatory approval for any of our product candidates may be withdrawn.

We have completed three Phase 2 trials for OCA: two in patients with PBC and one in patients with type 2 diabetes with co-morbid nonalcoholic fatty liver disease. We are currently in the process of enrolling patients into our Phase 3 POISE trial. Before we submit a NDA to the FDA or a MAA to the EMA for OCA for the treatment of patients with PBC, we must successfully complete this trial. In addition, we must complete other preclinical and clinical studies, such as a Phase 1 clinical trial in healthy volunteers to evaluate the effect of OCA on the heart's electrical cycle, known as the QT interval, studies to evaluate the interaction of OCA with other drugs and two-year, two-species carcinogenicity studies. We cannot predict whether our future trials and studies will be successful or whether regulators will agree with our conclusions regarding the preclinical studies and clinical trials we have conducted to date.

If we are unable to obtain approval from the FDA, the EMA or other regulatory agencies for OCA and our other product candidates, or if, subsequent to approval, we are unable to successfully commercialize OCA or our other product candidates, we will not be able to generate sufficient revenue to become profitable or to continue our operations.

We may never reach an agreement with the FDA on a surrogate endpoint for the accelerated approval of OCA for the treatment of PBC. The FDA, EMA and other regulators may require us to complete additional Phase 3 trials prior to the submission of an application for OCA for the treatment of PBC.

Typically, the FDA requires two pivotal clinical trials to approve a NDA. However, for OCA as a treatment for PBC, we currently plan to request accelerated approval from the FDA based on the Phase 3 POISE trial, the primary endpoint of which is a surrogate endpoint that we believe is reasonably likely to predict clinical benefit, therefore meeting the FDA's requirements for consideration under its accelerated approval regulation. However, the FDA has not yet provided any assurance that it will accept our approach, and we do not know if we will receive further written guidance from the FDA prior to submitting a NDA as to the acceptability of the POISE trial surrogate endpoint to support an approval of OCA for the treatment of PBC. We are currently seeking to build additional consensus regarding the clinical utility of the surrogate endpoint by working with a number of leading PBC academic centers to pool together and analyze their long-term PBC patient data. However, we may not be able to attain such consensus and, even if we do achieve such consensus, the supporting data may still not be accepted by the FDA in its consideration of the adequacy of our surrogate endpoint under a NDA for OCA for the treatment of PBC. The FDA has informed us that, in the context of considering OCA for potential accelerated approval, we will be required to conduct a Phase 3 clinical outcomes trial to confirm the clinical benefit of OCA in PBC by demonstrating the correlation of biochemical therapeutic response in patients taking OCA with a significant reduction in adverse clinical outcomes over time. We believe that this Phase 3 clinical outcomes trial will need to be substantially underway at the time we submit a NDA. It is possible that our NDA submission for regulatory approval will not be accepted by the FDA for review or, even if it is accepted for review, that there may be delays in the FDA's review process and that the FDA may determine that our NDA does not merit the approval of OCA for the treatment of PBC, in which case the FDA may require that we conduct and/or complete additional clinical trials and preclinical studies before it will reconsider our application for approval.

Because the FDA normally requires two pivotal clinical trials to approve a NDA, even if we achieve favorable results in our ongoing POISE trial, the FDA may not accept this trial as an adequate basis for approval and require that we conduct and complete a second Phase 3 clinical trial before considering a NDA for OCA for the treatment of PBC. Furthermore, the EMA and regulatory authorities in other countries in which we may seek approval for, and market, OCA, may require additional preclinical studies and/or clinical trials prior to granting approval. It may be expensive and time consuming to conduct and complete additional preclinical studies and clinical trials that the FDA, EMA and other regulatory authorities may require us to perform. As such, any requirement by the FDA, EMA or other regulatory authorities that we conduct additional preclinical studies or clinical trials could materially and adversely affect our business, financial condition and results of operations. Furthermore, even if we receive regulatory approval of OCA for the treatment of PBC, the labeling for OCA in the United States, Europe or other countries in which we seek approval may include limitations that could impact the commercial success of OCA.

Delays in the commencement, enrollment and completion of clinical trials could result in increased costs to us and delay or limit our ability to obtain regulatory approval for OCA and our other product candidates.

Delays in the commencement, enrollment and completion of clinical trials could increase our product development costs or limit the regulatory approval of our product candidates. We are currently enrolling patients for our Phase 3 POISE trial. We currently expect results from the trial to be available by mid-2014. Although we anticipate that the net proceeds from our IPO, together with existing cash and cash equivalents, , and interest on our cash balances, will be sufficient to fund our projected operating requirements through the completion of our POISE trial, we may not be able to complete this trial on time or we may be required to conduct additional clinical trials or preclinical studies not currently planned to receive approval for OCA as a treatment for PBC, in which case we would require additional funding. In addition, we do not know whether any future trials or studies of our other product candidates, including any confirmatory clinical trial of OCA, will begin on time or will be completed on schedule, if at all. The commencement, enrollment and completion of clinical trials can be delayed or suspended for a variety of reasons, including:

- inability to obtain sufficient funds required for a clinical trial;
- inability to reach agreements on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical holds, other regulatory objections to commencing or continuing a clinical trial or the inability to obtain regulatory approval to commence a clinical trial in countries that require such approvals;
- discussions with the FDA or non-U.S. regulators regarding the scope or design of our clinical trials;
- inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indications targeted by our product candidates;
- inability to obtain approval from institutional review boards, or IRBs, to conduct a clinical trial at their respective sites;
- severe or unexpected drug-related adverse effects experienced by patients;
- inability to timely manufacture sufficient quantities of the product candidate required for a clinical trial;
-

difficulty recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including meeting the enrollment criteria for our study and competition from other clinical trial programs for the same indications as our product candidates; and

- inability to retain enrolled patients after a clinical trial is underway.

For example, in the past, we experienced delays in our Phase 2 clinical trial of OCA given as a monotherapy to patients with PBC because we were unable to find and enroll a sufficient number of trial patients who met the specific enrollment criteria in accordance with our anticipated trial schedule.

Changes in regulatory requirements and guidance may also occur and we or any of our collaborators may need to amend clinical trial protocols to reflect these changes with appropriate regulatory authorities. Amendments may require us or any of our collaborators to resubmit clinical trial protocols to IRBs for re-examination, which may impact the costs, timing or successful completion of a clinical trial. In addition, a clinical trial may be suspended or terminated at any time by us, our current or future collaborators, the FDA or other regulatory authorities due to a number of factors, including:

- our failure or the failure of our collaborators to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- unforeseen safety issues or any determination that a clinical trial presents unacceptable health risks;
- lack of adequate funding to continue the clinical trial due to unforeseen costs or other business decisions; and
- a breach of the terms of any agreement with, or for any other reason by, current or future collaborators that have responsibility for the clinical development of any of our product candidates, including DSP and Servier.

In addition, if we or any of our collaborators are required to conduct additional clinical trials or other preclinical studies of our product candidates beyond those contemplated, our ability to obtain regulatory approval of these product candidates and generate revenue from their sales would be similarly harmed.

Clinical failure can occur at any stage of clinical development and we have never conducted a Phase 3 trial or submitted a NDA or MAA before. The results of earlier clinical trials are not necessarily predictive of future results and any product candidate we, DSP, Servier or our potential future collaborators advance through clinical trials may not have favorable results in later clinical trials or receive regulatory approval.

Clinical failure can occur at any stage of our clinical development. Clinical trials may produce negative or inconclusive results, and we or our collaborators may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. Success in preclinical studies and early clinical trials does not ensure that subsequent clinical trials will generate the same or similar results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in Phase 3 clinical trials, even after seeing promising results in earlier clinical trials.

Both of our Phase 2 clinical trials of OCA in PBC patients showed statistically significant results against a primary endpoint that is similar to the endpoint of our Phase 3 POISE trial protocol currently underway. However, in our Phase 2 PBC trials, the primary endpoint was a reduction in alkaline phosphatase, or ALP, to a threshold below 1.5 times upper limit normal, or ULN, compared to placebo after 12 weeks of treatment, but the primary endpoint for our POISE trial is both a reduction in ALP to below a threshold of 1.67 times ULN, with a minimum of 15% reduction in ALP from baseline, and a normal bilirubin level, compared to placebo after 12 months of therapy. We cannot assure you that our POISE trial will achieve positive results. Moreover, the fact that a retrospective analysis of the data from our Phase 2 PBC trials appears to demonstrate that the defined endpoint in our POISE trial was achieved based on the Phase 2 data does not mean that this endpoint will be successfully achieved in the POISE trial.

In addition, the design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well-advanced. We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support regulatory approval. Further, clinical trials of potential products often reveal that it is not practical or feasible to continue development efforts.

If OCA or our other product candidates are found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for them and our business would be harmed. For example, if the results of our Phase 3 POISE trial of OCA do not achieve the primary efficacy endpoints or demonstrate expected safety, the prospects for approval of OCA would be materially and adversely affected.

In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in composition of the patient populations, adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. We do not know whether any Phase 2, Phase 3 or other clinical trials we or any of our collaborators may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates. If we are unable to bring any of our current or future product candidates to market, or to acquire any marketed, previously approved products, our ability to create long-term stockholder value will be limited.

Our product candidates may have undesirable side effects which may delay or prevent marketing approval, or, if approval is received, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.

A substance that binds to a receptor of a cell and triggers a response by that cell is called an agonist. OCA has been shown to be a potent agonist of the farnesoid X receptor, or FXR. With the exception of the bile acid CDCA, which has been approved to treat cholesterol gallstone dissolution and a rare lipid storage disease, there are no approved FXR agonists and the adverse effects from long-term exposure to this drug class are unknown. Unforeseen side effects

from any of our product candidates could arise either during clinical development or, if approved, after the approved product has been marketed. The most common side effects observed in clinical trials of OCA were pruritus, or itching, headaches, fatigue, nausea, constipation and diarrhea. In our Phase 2 PBC clinical trial of OCA in combination with ursodiol, approximately 8% of the patients enrolled in the 10 milligram (mg) and 25 mg dose groups withdrew from the trial due to severe pruritus. At the 50 mg dose, approximately 25% of the patients withdrew from the trial due to severe pruritus. Additional or unforeseen side effects from these or any of our other product candidates could arise either during clinical development or, if approved, after the approved product has been marketed.

The range and potential severity of possible side effects from systemic therapies is significant. The results of future clinical trials may show that our product candidates cause undesirable or unacceptable side effects, which could interrupt, delay or halt clinical trials, and result in delay of, or failure to obtain, marketing approval from the FDA and other regulatory authorities, or result in marketing approval from the FDA and other regulatory authorities with restrictive label warnings.

If any of our product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products:

- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- we may be required to change instructions regarding the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- regulatory authorities may require us to take our approved product off the market;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us, DSP, Servier or our potential future collaborators from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from the sale of our products.

Reimbursement decisions by third-party payors may have an adverse effect on pricing and market acceptance. If there is not sufficient reimbursement for our products, it is less likely that they will be widely used.

Market acceptance and sales of OCA or any other product candidates that we develop, if approved, will depend on reimbursement policies and may be affected by future healthcare reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will cover and establish payment levels. We cannot be certain that reimbursement will be available for OCA or any other product candidates that we develop. Also, we cannot be certain that reimbursement policies will not reduce the demand for, or the price paid for, our products. If reimbursement is not available or is available on a limited basis, we may not be able to successfully commercialize OCA or any other product candidates that we develop.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation established Medicare Part D, which expanded Medicare coverage for outpatient prescription drug purchases by the elderly but provided authority for limiting the number of drugs that will be covered in any therapeutic class. The MMA also introduced a new reimbursement methodology based on average sales prices for physician- administered drugs. Any negotiated prices for our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

The United States and several other jurisdictions are considering, or have already enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access to healthcare. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. We expect to experience pricing pressures in connection with the sale of OCA and any other products that we develop, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, ACA, became law in the United States. The goal of ACA is to reduce the cost of health care and substantially change the way health care is financed by both governmental and private insurers. While we cannot predict what impact on federal reimbursement policies this legislation will have in

general or on our business specifically, the ACA may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of OCA or any future product candidates. In addition, although the United States Supreme Court recently upheld the constitutionality of most of the ACA, some states have indicated that they intend to not implement certain sections of the ACA, and some members of the U.S. Congress are still working to repeal the ACA. We cannot predict whether these challenges will continue or other proposals will be made or adopted, or what impact these efforts may have on us.

If we do not obtain protection under the Hatch-Waxman Act and similar legislation outside of the United States by extending the patent terms and obtaining data exclusivity for our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of OCA and our other product candidates, if any, one or more of our U.S. patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially. In the event that we are unable to obtain any patent term extensions, the issued composition of matter patents for OCA are expected to expire in 2022 assuming they withstand any challenge. We expect that the other patents and patent applications for the OCA portfolio, if issued, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, would expire from 2022 to 2028.

If we market products in a manner that violates healthcare fraud and abuse laws, or if we violate government price reporting laws, we may be subject to civil or criminal penalties.

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal healthcare laws, commonly referred to as “fraud and abuse” laws, have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. Other jurisdictions such as Europe have similar laws. These laws include false claims and anti-kickback statutes. If we market our products and our products are paid for by governmental programs, it is possible that some of our business activities could be subject to challenge under one or more of these laws.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service covered by Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers or formulary managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Most states also have statutes or regulations similar to the federal anti-kickback law and federal false claims laws, which apply to items and services covered by Medicaid and other state programs, or, in several states, apply regardless of the payor. Administrative, civil and criminal sanctions may be imposed under these federal and state laws.

Over the past few years, a number of pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of promotional and marketing activities, such as: providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates.

If the FDA and EMA and other regulatory agencies do not approve the manufacturing facilities of our future contract manufacturers for commercial production, we may not be able to commercialize any of our product candidates.

We do not intend to manufacture the pharmaceutical products that we plan to sell. We currently have agreements with contract manufacturers for the production of the active pharmaceutical ingredients and the formulation of sufficient quantities of drug product for our Phase 3 POISE trial of OCA for the treatment of PBC and the other trials and preclinical studies that we believe we will need to conduct prior to seeking regulatory approval. However, we do not have agreements for commercial supplies of OCA or any of our other product candidates and we may not be able to reach agreements with these or other contract manufacturers for sufficient supplies to commercialize OCA if it is approved. Additionally, the facilities used by any contract manufacturer to manufacture OCA or any of our other product candidates must be the subject of a satisfactory inspection before the FDA or the regulators in other jurisdictions approve the product candidate manufactured at that facility. We are completely dependent on these third-party manufacturers for compliance with the requirements of U.S. and non-U.S. regulators for the manufacture of our finished products. If our manufacturers cannot successfully manufacture material that conform to our specifications and current good manufacturing practice requirements of any governmental agency whose jurisdiction to which we are subject, our product candidates will not be approved or, if already approved, may be subject to recalls. Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured the product candidates, including:

- the possibility that we are unable to enter into a manufacturing agreement with a third party to manufacture our product candidates;

- the possible breach of the manufacturing agreements by the third parties because of factors beyond our control; and

- the possibility of termination or nonrenewal of the agreements by the third parties before we are able to arrange for a qualified replacement third-party manufacturer.

Any of these factors could cause the delay of approval or commercialization of our product candidates, cause us to incur higher costs or prevent us from commercializing our product candidates successfully. Furthermore, if any of our product candidates are approved and contract manufacturers fail to deliver the required commercial quantities of finished product on a timely basis and at commercially reasonable prices and we are unable to find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality and on a timely basis, we would likely be unable to meet demand for our products and could lose potential revenue. It may take several years to establish an alternative source of supply for our product candidates and to have any such new source approved by the government agencies that regulate our products.

Even if our product candidates receive regulatory approval, we may still face future development and regulatory difficulties.

Our product candidates, if approved, will also be subject to ongoing regulatory requirements for labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information. In addition, approved products, manufacturers and manufacturers' facilities are required to comply with extensive FDA and EMA requirements and requirements of other similar agencies, including ensuring that quality control and manufacturing procedures conform to current Good Manufacturing Practices, or cGMPs. As such, we and our contract manufacturers are subject to continual review and periodic inspections to assess compliance with cGMPs. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. We will also be required to report certain adverse reactions and production problems, if any, to the FDA and EMA and other similar agencies and to comply with certain requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. Accordingly, we may not promote our approved products, if any, for indications or uses for which they are not approved.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, it may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us or our collaborators to enter into a consent decree or permanent injunction, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- impose other administrative or judicial civil or criminal penalties;
- withdraw regulatory approval;
- refuse to approve pending applications or supplements to approved applications filed by us, DSP, Servier or our potential future collaborators;
- impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products.

Risks Relating to the Commercialization of Our Products

Even if approved, our product candidates may not achieve broad market acceptance among physicians, patients and healthcare payors, and as a result our revenues generated from their sales may be limited.

The commercial success of OCA or our other product candidates, if approved, will depend upon their acceptance among the medical community, including physicians, health care payors and patients. For PBC, the current standard of care is ursodeoxycholic acid, which is available generically as ursodiol. In order for OCA to be commercially

successful, we will need to demonstrate that it is safe and effective for the treatment of patients who have an inadequate response to or who are unable to tolerate ursodiol, referred to as second line treatment, and is more effective than any other alternatives that may be developed as a second line treatment for PBC, particularly given the planned much higher price that we anticipate charging for OCA compared to the price of generically available ursodiol. The degree of market acceptance of our product candidates will depend on a number of factors, including:

- changes in the standard of care or availability of alternative therapies at similar or lower costs for the targeted indications for any of our product candidates, such as ursodiol for the treatment of PBC;
- limitations in the approved clinical indications for our product candidates;
- demonstrated clinical safety and efficacy compared to other products;
- lack of significant adverse side effects;
- sales, marketing and distribution support;
- availability of reimbursement from managed care plans and other third-party payors;
- timing of market introduction and perceived effectiveness of competitive products;
- the degree of cost-effectiveness;
- availability of alternative therapies at similar or lower cost, including generics and over-the-counter products;
- the extent to which our product candidates are approved for inclusion on formularies of hospitals and managed care organizations;
- whether our product candidates are designated under physician treatment guidelines for the treatment of the indications for which we have received regulatory approval;
- adverse publicity about our product candidates or favorable publicity about competitive products;
- convenience and ease of administration of our product candidates; and
- potential product liability claims.

If our product candidates are approved, but do not achieve an adequate level of acceptance by physicians, patients, the medical community and healthcare payors, sufficient revenue may not be generated from these products and we may not become or remain profitable. In addition, efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

We have no sales, marketing or distribution experience and we will have to invest significant resources to develop those capabilities or enter into acceptable third-party sales and marketing arrangements.

We have no sales, marketing or distribution experience. To develop internal sales, distribution and marketing capabilities, we will have to invest significant amounts of financial and management resources, some of which will be committed prior to any confirmation that OCA or any of our other product candidates will be approved. For product candidates where we decide to perform sales, marketing and distribution functions ourselves or through third parties, we could face a number of additional risks, including:

- we or our third-party sales collaborators may not be able to attract and build an effective marketing or sales force;
- the cost of securing or establishing a marketing or sales force may exceed the revenues generated by any products; and
- our direct sales and marketing efforts may not be successful.

We have entered into an agreement with DSP for the development and commercialization of OCA in Japan and China and other potential Asian countries, if approved, and have entered into an agreement with Servier to assist in the development and commercialization of certain of our earlier stage agonists of a dedicated bile acid receptor called TGR5 outside of the United States and Japan, if approved, and may elect to seek additional strategic collaborators for our product candidates. We may have limited or no control over the sales, marketing and distribution activities of these third parties. Our future revenues may depend heavily on the success of the efforts of these third parties.

If any of our current strategic collaborators fails to perform its obligations or terminates its agreement with us, the development and commercialization of the product candidates under such agreement could be delayed or terminated and our business could be substantially harmed.

We currently have strategic collaborations in place relating to certain of our product candidates. We entered into an exclusive license agreement with DSP regarding the development and commercialization of OCA for PBC and NASH in Japan and China and provided DSP with an option to extend its exclusive license to different indications as well as certain other Asian countries. We entered into a strategic collaboration with Servier initially focused on the identification and optimization of novel TGR5 agonists for the treatment of type-2 diabetes and other associated disorders. These strategic collaborations may not be scientifically or commercially successful due to a number of important factors, including the following:

- DSP and Servier have significant discretion in determining the efforts and resources that each will apply to their strategic collaboration with us. The timing and amount of any cash payments, milestones and royalties that we may receive under such agreements will depend on, among other things, the efforts, allocation of resources and successful development and commercialization of our product candidates by DSP and Servier under their respective agreements;

- Our agreement with Servier provides it with wide discretion in deciding which novel compounds to advance through the preclinical and clinical development process. It is possible for Servier to reject certain compounds at any point in the research, development and clinical trial process without triggering a termination of their agreement with us. In the event of any such decision, our business and prospects may be adversely affected due to our inability to progress such compounds ourselves;

- Our agreement with DSP restricts it from developing or commercializing any FXR agonist to treat PBC or NASH during the term of the agreement other than pursuant to the DSP agreement and our agreement with Servier restricts it from developing or commercializing any TGR5 receptor agonist during the term of the agreement other than pursuant to the Servier agreement. Subject to these restrictions, it is possible that DSP or Servier may develop and commercialize, either alone or with others, or be acquired by a company that has, products that are similar to or competitive with the product candidates that they license from us;

- DSP or Servier may change the focus of their development and commercialization efforts or pursue higher-priority programs;

- DSP or Servier may, under specified circumstances, terminate their strategic collaborations with us on short notice and for circumstances outside of our control, which could make it difficult for us to attract new strategic collaborators or adversely affect how we are perceived in the scientific and financial communities;

- DSP and Servier have, under certain circumstances, the right to maintain or defend our intellectual property rights licensed to them in their territories, and, although we may have the right to assume the maintenance and defense of our intellectual property rights if our strategic collaborators do not, our ability to do so may be compromised by our strategic collaborators' acts or omissions;

- DSP or Servier may utilize our intellectual property rights in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential liability; and

- DSP or Servier may not comply with all applicable regulatory requirements, or fail to report safety data in accordance with all applicable regulatory requirements.

If either DSP or Servier fails to develop or effectively commercialize OCA or any TGR5 compounds, respectively, we may not be able to replace them with another collaborator. We may also be unable to obtain, on terms acceptable to us, a license from such strategic collaborator to any of its intellectual property that may be necessary or useful for us to continue to develop and commercialize a product candidate. Any of these events could have a material adverse effect on our business, results of operations and our ability to achieve future profitability, and could cause our stock price to decline.

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We may not be successful in establishing and maintaining development and commercialization collaborations, which could adversely affect our ability to develop certain of our product candidates and our financial condition and operating results.

Because developing pharmaceutical products, conducting clinical trials, obtaining regulatory approval, establishing manufacturing capabilities and marketing approved products are expensive, we have entered into, and may seek to enter into, collaborations with companies that have more experience. For example, we have entered into collaborations with DSP for OCA and Servier for our earlier stage TGR5 program. We may establish additional collaborations for development and commercialization of OCA in territories outside of those licensed by DSP or for our earlier stage TGR5 program in the United States or Japan and product candidates and research programs, including INT-767 and INT-777. Additionally, if any of our product candidates receives marketing approval, we may enter into sales and marketing arrangements with third parties with respect to our unlicensed territories. If we are unable to maintain our existing arrangements or enter into any new such arrangements on acceptable terms, if at all, we may be unable to effectively market and sell our products in our target markets. We expect to face competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement and they may require substantial resources to maintain. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements for the development of our product candidates.

When we collaborate with a third party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party. For example, DSP has the exclusive rights to OCA in Japan and China and the option to exclusively license OCA in several other Asian countries. Our collaboration partner may not devote sufficient resources to the commercialization of our product candidates or may otherwise fail in their commercialization. The terms of any collaboration or other arrangement that we establish may not be favorable to us. In addition, any collaboration that we enter into, including our collaborations with DSP and Servier, may be unsuccessful in the development and commercialization of our product candidates. In some cases, we may be responsible for continuing preclinical and initial clinical development of a product candidate or research program under a collaboration arrangement, and the payment we receive from our collaboration partner may be insufficient to cover the cost of this development. If we are unable to reach agreements with suitable collaborators for our product candidates, we would face increased costs, we may be forced to limit the number of our product candidates we can commercially develop or the territories in which we commercialize them and we might fail to commercialize products or programs for which a suitable collaborator cannot be found. If we fail to achieve successful collaborations, our operating results and financial condition will be materially and adversely affected.

If we fail to develop OCA for additional indications, our commercial opportunity will be limited.

To date, we have focused the majority of our development efforts on the development of OCA for the second line treatment of PBC. One of our strategies is to pursue clinical development of OCA for other orphan and more common indications, to the extent that we have sufficient funding.

PBC is a rare disease and, as a result, the market size for treatments of PBC is limited. Furthermore, because a significant proportion of PBC patients do not exhibit any symptoms at the time of diagnosis, PBC may be left undiagnosed for a significant period of time. Due to these factors, our ability to grow revenues will be dependent on our ability to successfully develop and commercialize OCA for the treatment of additional indications. The completion of development, securing of approval and commercialization of OCA for additional indications will require substantial additional funding and is prone to the risks of failure inherent in drug development. We cannot provide you any assurance that we will be able to successfully advance any of these indications through the development process. Even if we receive FDA approval to market OCA for the treatment of any of these additional indications, we cannot assure you that any such additional indications will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize OCA for these additional indications, our commercial opportunity will be limited and our business prospects will suffer.

If serious adverse events or other undesirable side effects are identified during the development of OCA for one indication, we may need to abandon our development of OCA for other indications.

Product candidates in clinical stages of development have a high risk of failure. We cannot predict when or if OCA will prove effective or safe in humans or will receive regulatory approval. To date, the most common side effects observed in clinical trials of OCA were pruritus, headaches, fatigue, constipation and diarrhea. New side effects could, however, be identified as we expand our clinical trials for OCA to other indications. If new side effects are found during the development of OCA for any indication, if known side effects are shown to be more severe than previously observed or if OCA is found to have other unexpected characteristics, we may need to abandon our development of OCA for PBC and other potential indications. We cannot assure you that additional or more severe adverse side effects with respect to OCA will not develop in future clinical trials, which could delay or preclude regulatory approval of OCA or limit its commercial use.

Risks Relating to Our Business and Strategy

We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We have competitors in the United States, Europe and other jurisdictions, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical and generic drug companies and universities and other research institutions. Many of our competitors have greater financial and other resources, such as larger research and development staff and more experienced marketing and manufacturing organizations. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing pharmaceutical products. These companies also have significantly greater research, sales and marketing capabilities and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or FDA approval or discovering, developing and commercializing drugs for the chronic liver and other diseases that we are targeting before we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Some of the pharmaceutical and biotechnology companies we expect to compete with include Astellas Pharma US, Inc., AstraZeneca, Dr. Falk Pharma GmbH, Eli Lilly, Exelixis, Inc., Galmed Medical Research Ltd., Immuron Ltd., Johnson & Johnson, Mochida Pharmaceutical Co., Ltd., NasVax Ltd., NovImmune SA., Phenex Pharmaceuticals AG, Raptor Pharmaceutical Corp., Salix Pharmaceuticals, Inc. and Tioga Pharmaceuticals, Inc. In addition, many universities and private and public research institutes may become active in our target disease areas. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, technologies and drug products that are more effective or less costly than OCA or any other product candidates that we are currently developing or that we may develop, which could render our products obsolete and noncompetitive.

We believe that our ability to successfully compete will depend on, among other things:

- the results of our and our strategic collaborators' clinical trials and preclinical studies;
- our ability to recruit and enroll patients for our clinical trials;
- the efficacy, safety and reliability of our product candidates;
- the speed at which we develop our product candidates;

- our ability to design and successfully execute appropriate clinical trials;
  - our ability to maintain a good relationship with regulatory authorities;
  - the timing and scope of regulatory approvals, if any;
- our ability to commercialize and market any of our product candidates that receive regulatory approval;
- the price of our products;
  - adequate levels of reimbursement under private and governmental health insurance plans, including Medicare;
- our ability to protect intellectual property rights related to our products;
- our ability to manufacture and sell commercial quantities of any approved products to the market; and
  - acceptance of our product candidates by physicians and other health care providers.

If our competitors market products that are more effective, safer or less expensive than our future products, if any, or that reach the market sooner than our future products, if any, we may not achieve commercial success. In addition, the biopharmaceutical industry is characterized by rapid technological change. Because our research approach integrates many technologies, it may be difficult for us to stay abreast of the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical.

We depend on third-party contractors for a substantial portion of our operations and may not be able to control their work as effectively as if we performed these functions ourselves.

We outsource substantial portions of our operations to third-party service providers, including the conduct of preclinical studies and clinical trials, collection and analysis of data and manufacturing. Our agreements with third-party service providers and CROs are on a study-by-study and project-by-project basis. Typically, we may terminate the agreements with notice and are responsible for the supplier's previously incurred costs. In addition, any CRO that we retain will be subject to the FDA's and EMA's regulatory requirements and similar standards outside of

the United States and Europe and we do not have control over compliance with these regulations by these providers. Consequently, if these providers do not adhere to applicable governing practices and standards, the development and commercialization of our product candidates could be delayed or stopped, which could severely harm our business and financial condition.

Because we have relied on third parties, our internal capacity to perform these functions is limited to management oversight. Outsourcing these functions involves the risk that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. Several years ago, we experienced difficulties with a third-party contract manufacturer for OCA, including delays in receiving adequate clinical trial supplies as requested within the requested time periods. We subsequently replaced this manufacturer with other third-party contract manufacturers for OCA. Although we have not experienced any significant difficulties with our third-party contractors since then, it is possible that we could experience difficulties in the future. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. There are a limited number of third-party service providers that specialize or have the expertise required to achieve our business objectives. Identifying, qualifying and managing performance of third-party service providers can be difficult, time consuming and cause delays in our development programs. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor third-party service providers. To the extent we are unable to identify, retain and successfully manage the performance of third-party service providers in the future, our business may be adversely affected, and we may be subject to the imposition of civil or criminal penalties if their conduct of clinical trials violates applicable law.

A variety of risks associated with our planned international business relationships could materially adversely affect our business.

We have entered into an agreement with DSP for the development of OCA and with Servier for our earlier stage TGR5 program, and we may enter into agreements with other third parties for the development and commercialization of OCA or our other product candidates in international markets. International business relationships subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including:

- differing regulatory requirements for drug approvals internationally;
- potentially reduced protection for intellectual property rights;
- potential third-party patent rights in countries outside of the United States;
- the potential for so-called "parallel importing," which is what occurs when a local seller, faced with relatively high local prices, opts to import goods from another jurisdiction with relatively low prices, rather than buying them locally;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability, particularly in non-U.S. economies and markets, including several countries in Europe;
- compliance with tax, employment, immigration and labor laws for employees traveling abroad;
- taxes in other countries;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and

- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

We will need to expand our operations and increase the size of our company, and we may experience difficulties in managing growth.

As we increase the number of ongoing product development programs and advance our product candidates through preclinical studies and clinical trials, we will need to increase our product development, scientific and administrative headcount to manage these programs. In addition, to meet our obligations as a public company, we will need to increase our general and administrative capabilities. Our management, personnel and systems currently in place may not be adequate to support this future growth. Our need to effectively manage our operations, growth and various projects requires that we:

- successfully attract and recruit new employees or consultants with the expertise and experience we will require;
- manage our clinical programs effectively, which we anticipate being conducted at numerous clinical sites;
- develop a marketing and sales infrastructure; and
- continue to improve our operational, financial and management controls, reporting systems and procedures.

If we are unable to successfully manage this growth and increased complexity of operations, our business may be adversely affected.

We may not be able to manage our business effectively if we are unable to attract and retain key personnel and consultants.

We may not be able to attract or retain qualified management, finance, scientific and clinical personnel and consultants due to the intense competition for qualified personnel and consultants among biotechnology, pharmaceutical and other businesses. If we are not able to attract and retain necessary personnel and consultants to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the development, regulatory, commercialization and business development expertise of Mark Pruzanski, our co-founder and president and chief executive officer; David Shapiro, our chief medical officer; Barbara Duncan, our chief financial officer, treasurer and secretary; Luciano Adorini, our chief scientific officer; and our other key employees and consultants, such as Professor Roberto Pellicciari, our co-founder who provides ongoing consulting services to us. If we lose one or more of our executive officers or key employees or consultants, our ability to implement our business strategy successfully could be seriously harmed. Any of our executive officers or key employees or consultants may terminate their employment at any time. Replacing executive officers, key employees and consultants may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize products successfully. Competition to hire and retain employees and consultants from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel and consultants. Our failure to retain key personnel or consultants could materially harm our business.

We have scientific and clinical advisors and consultants who assist us in formulating our research, development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us and typically they will not enter into non-compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours.

Failure to build our finance infrastructure and improve our accounting systems and controls could impair our ability to comply with the financial reporting and internal controls requirements for publicly traded companies.

As a public company, we operate in an increasingly demanding regulatory environment, which requires us to comply with the Sarbanes-Oxley Act of 2002, and the related rules and regulations of the Securities and Exchange Commission, expanded disclosure requirements, accelerated reporting requirements and more complex accounting rules. Company responsibilities required by the Sarbanes-Oxley Act include establishing corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. Effective internal controls

are necessary for us to produce reliable financial reports and are important to help prevent financial fraud.

We have begun implementing our system of internal controls over financial reporting and preparing the documentation necessary to perform the evaluation needed to comply with Section 404(a) of the Sarbanes-Oxley Act. However, we anticipate that we will need to retain additional finance capabilities and build our financial infrastructure as we transition to operating as a public company, including complying with the requirements of Section 404 of the Sarbanes-Oxley Act. We plan to continue improving our financial infrastructure with the retention of additional financial and accounting capabilities, the enhancement of internal controls and additional training for our financial and accounting staff.

Section 404(a) of the Sarbanes-Oxley Act requires annual management assessments of the effectiveness of our internal control over financial reporting, starting with the second annual report that we would expect to file with the Securities and Exchange Commission. However, for as long as we remain an “emerging growth company” as defined in the JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not “emerging growth companies” including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act. We may take advantage of these reporting exemptions until we are no longer an “emerging growth company.” We will remain an “emerging growth company” until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1 billion or more; (ii) December 31, 2017; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission.

Until we are able to expand our finance and administrative capabilities and establish necessary financial reporting infrastructure, we may not be able to prepare and disclose, in a timely manner, our financial statements and other required disclosures or comply with the Sarbanes-Oxley Act or existing or new reporting requirements. If we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed and investors could lose confidence in our reported financial information.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading, which could significantly harm our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with the regulations of the FDA and non-U.S. regulators, provide accurate information to the FDA and non-U.S. regulators, comply with health care fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of conduct, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for a product candidate and may have to limit its commercialization.

The use of our product candidates in clinical trials and the sale of any products for which we may obtain marketing approval expose us to the risk of product liability claims. Product liability claims may be brought against us or our collaborators by participants enrolled in our clinical trials, patients, health care providers or others using, administering or selling our products. If we cannot successfully defend ourselves against any such claims, we would incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;

- decreased demand for our product candidates and loss of revenues;
- impairment of our business reputation;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize our product candidates.

We have obtained limited product liability insurance coverage for our clinical trials in the United States and in selected other jurisdictions where we are conducting clinical trials. Our product liability insurance coverage for clinical trials in the United States is currently limited to an aggregate of $10 million and outside of the United States we have coverage for lesser amounts that vary by country. As such, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to product liability. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain marketing approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash resources and adversely affect our business.

Our insurance policies are expensive and only protect us from some business risks, which will leave us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, employment practices liability, property, auto, workers' compensation, products liability and directors' and officers' insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations.

If we engage in an acquisition, reorganization or business combination, we will incur a variety of risks that could adversely affect our business operations or our stockholders.

From time to time we have considered, and we will continue to consider in the future, strategic business initiatives intended to further the expansion and development of our business. These initiatives may include acquiring businesses, technologies or products or entering into a business combination with another company. If we pursue such a strategy, we could, among other things:

- issue equity securities that would dilute our current stockholders' percentage ownership;
- incur substantial debt that may place strains on our operations;
- spend substantial operational, financial and management resources to integrate new businesses, technologies and products;
- assume substantial actual or contingent liabilities;
- reprioritize our development programs and even cease development and commercialization of our product candidates; or
- merge with, or otherwise enter into a business combination with, another company in which our stockholders would receive cash and/or shares of the other company on terms that certain of our stockholders may not deem desirable.

Although we intend to evaluate and consider acquisitions, reorganizations and business combinations in the future, we have no agreements or understandings with respect to any acquisition, reorganization or business combination at this time.

Risks Relating to Our Intellectual Property

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection. If our patent position does not adequately protect our product candidates, others could compete against us more directly, which would harm our business, possibly materially.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our current and future product candidates and the methods used to manufacture them, as well as successfully defending these patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

The patent positions of biotechnology and pharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged to date in the United States or in many jurisdictions outside of the United States. Changes in either the patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be enforced in the patents that may be issued from the applications we currently or may in the future own or license from third parties. Further, if any patents we obtain or license are deemed invalid and unenforceable, our ability to commercialize or license our technology could be adversely affected.

Others have filed, and in the future are likely to file, patent applications covering products and technologies that are similar, identical or competitive to ours or important to our business. We cannot be certain that any patent application owned by a third party will not have priority over patent applications filed or in-licensed by us, or that we or our licensors will not be involved in interference, opposition or invalidity proceedings before U.S. or non-U.S. patent offices.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to develop a platform similar to, or better than, ours in a way that is not covered by the claims of our patents;
- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of our patents;
- we might not have been the first to make the inventions covered by our pending patent applications;
- we might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- any patents that we obtain may not provide us with any competitive advantages;
- we may not develop additional proprietary technologies that are patentable; or
- the patents of others may have an adverse effect on our business.

As of November 15, 2012, we were the owner of record of 46 issued or granted U.S. and non-U.S. patents relating to OCA with claims directed to pharmaceutical compounds, pharmaceutical compositions, methods of making these compounds, and methods of using these compounds in various indications. We were also the owner of record of 11 pending U.S. and non-U.S. patent applications relating to OCA in these areas.

In addition, as of November 15, 2012, we were the owner of record of issued or granted U.S. and non-U.S. patents relating to our product candidates other than OCA, with claims directed to pharmaceutical compounds, pharmaceutical compositions and methods of using these compounds in various indications. We were also the owner of record of pending U.S. and non-U.S. patent applications relating to such other product candidates in these areas.

Patents covering the composition of matter of OCA expire in 2022 if the appropriate maintenance fee renewal, annuity, or other government fees are paid. We expect that the other patents and patent applications for the OCA portfolio, if issued, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, would expire from 2022 to 2028. We expect the issued INT-767 composition of matter patent in the United States, if the appropriate maintenance fee, renewal, annuity, or other governmental fees are paid, to expire in 2029. We expect the other pending patent applications in the INT-767 portfolio, if issued, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire in 2027. We expect the issued INT-777 composition of matter patent in the United States, if the appropriate maintenance fee, renewal, annuity, or other governmental fees are paid, to expire in 2030. We expect the other pending patent applications in the INT-777 portfolio, if issued, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire from 2028 to 2029.

Without patent protection on the composition of matter of our product candidates, our ability to assert our patents to stop others from using or selling our product candidates in a non-pharmaceutically acceptable formulation may be limited.

Due to the patent laws of a country, or the decisions of a patent examiner in a country, or our own filing strategies, we may not obtain patent coverage for all of our product candidates or methods involving these candidates in the parent patent application. We plan to pursue divisional patent applications or continuation patent applications in the United States and other countries to obtain claim coverage for inventions which were disclosed but not claimed in the parent patent application.

We may also rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or feasible. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.

If we choose to go to court to stop another party from using the inventions claimed in any patents we obtain, that individual or company has the right to ask the court to rule that such patents are invalid or should not be enforced against that third party. These lawsuits are expensive and would consume time and resources and divert the attention of managerial and scientific personnel even if we were successful in stopping the infringement of such patents. In addition, there is a risk that the court will decide that such patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of such patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe our rights to such patents. In addition, the U.S. Supreme Court has recently modified some tests used by the U.S. Patent and Trademark Office, or USPTO, in granting patents over the past 20 years, which may decrease the likelihood that we will be able to obtain patents and increase the likelihood of challenge of any patents we obtain or license.

We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing or increase the costs of commercializing our product candidates.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. We cannot guarantee that our products, or manufacture or use of our product candidates, will not infringe third-party patents. Furthermore, a third party may claim that we or our manufacturing or commercialization collaborators are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our product candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and scientific personnel. There is a risk that a court would decide that we or our commercialization collaborators are infringing the third party's patents and would order us or our collaborators to stop the activities covered by the patents. In that event, we or our commercialization collaborators may not have a viable way around the patent and may need to halt commercialization of the relevant product. In addition, there is a risk that a court will order us or our collaborators to pay the other party damages for having violated the other party's patents. In the future, we may agree to indemnify our commercial collaborators against certain intellectual property infringement claims brought by third parties. The pharmaceutical and biotechnology industries have produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform.

If we are sued for patent infringement, we would need to demonstrate that our products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, which may not be available, defend an infringement action or challenge

the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may incur substantial monetary damages, encounter significant delays in bringing our product candidates to market and be precluded from manufacturing or selling our product candidates.

We cannot be certain that others have not filed patent applications for technology covered by our pending applications, or that we were the first to invent the technology, because:

- some patent applications in the United States may be maintained in secrecy until the patents are issued;
- patent applications in the United States are typically not published until 18 months after the priority date; and
- publications in the scientific literature often lag behind actual discoveries.

Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent application may have priority over our patent applications, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if, unbeknownst to us, the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such inventions. Other countries have similar laws that permit secrecy of patent applications, and may be entitled to priority over our applications in such jurisdictions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees due to non-U.S. patent agencies. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers. If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of our technology and products could be significantly diminished.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

We rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA’s disclosure policies may change in the future, if at all. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

We have not yet registered our trademarks and failure to secure those registrations could adversely affect our business.

If we seek to register any of our trademarks, our trademark applications may not be allowed for registration or our registered trademarks may not be maintained or enforced. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many other jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would.

In addition, we have not yet proposed a proprietary name for any of our product candidates, including OCA, in any jurisdiction. Any proprietary name we propose to use with OCA in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

Risks Relating to Owning Our Common Stock

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

Since our initial listing on the NASDAQ Global Market on October 11, 2012, the trading market in our common stock has been extremely limited and substantially less liquid than the average trading market for companies quoted on the NASDAQ Global Market. The quotation of our common stock on the NASDAQ Global Market does not assure that a meaningful, consistent and liquid trading market currently exists. We cannot predict whether a more active market for our common stock will develop in the future. An absence of an active trading market could adversely affect our stockholders' ability to sell our common stock at current market prices in short time periods, or possibly at all. Additionally, market visibility for our common stock may be limited and such lack of visibility may have a depressive effect on the market price for our common stock. As of November 10, 2012, approximately 63.2% of our outstanding shares of common stock was held by our officers, directors, beneficial owners of 5% or more of our securities and their respective affiliates, which adversely affects the liquidity of the trading market for our common stock, in as much as federal securities laws restrict sales of our shares by these stockholders. If our affiliates continue to hold their shares of common stock, there will be limited trading volume in our common stock, which may make it more difficult for investors to sell their shares or increase the volatility of our stock price. In addition, 11,769,189 shares of common stock are currently restricted from resale under securities laws or as a result of lock-up agreements, further limiting the

liquidity of our common stock.

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

The market price of shares of our common stock could be subject to wide fluctuations in response to many risk factors listed in this section, and others beyond our control, including:

- results of our clinical trials;
- results of clinical trials of our competitors' products;
- regulatory actions with respect to our products or our competitors' products;
- actual or anticipated fluctuations in our financial condition and operating results;
- actual or anticipated changes in our growth rate relative to our competitors;
- actual or anticipated fluctuations in our competitors' operating results or changes in their growth rate;
- competition from existing products or new products that may emerge;
- announcements by us, our collaborators or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- issuance of new or updated research or reports by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- additions or departures of key management or scientific personnel;

- disputes or other developments related to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- market conditions for biopharmaceutical stocks in general; and
- general economic and market conditions.

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

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

As of November 10, 2012, Genextra S.p.A., together with its affiliates, whom we refer to collectively as Genextra, is our largest stockholder. Genextra beneficially owns shares representing approximately 43.6% of our common stock. Accordingly, Genextra exerts significant influence over us and any action requiring the approval of the holders of our common stock, including the election of directors and approval of significant corporate transactions. This concentration of voting power makes it less likely that any other holder of common stock or directors of our business will be able to affect the way we are managed and could delay or prevent an acquisition of us on terms that other stockholders may desire. In addition, if Genextra obtains a majority of our common stock, Genextra would be able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, Genextra would be able to control the election of directors and approval of any merger, consolidation, sale of all or substantially all of our assets or other business combination or reorganization. In addition, if Genextra obtains a majority of our common stock, we would be deemed a "controlled company" for purposes of NASDAQ listing requirements. Under NASDAQ rules, a "controlled company" may elect not to comply with certain NASDAQ corporate governance requirements, including (i) the requirement that a majority of our board of directors consist of independent directors, (ii) the requirement that the compensation of our officers be determined or recommended to the board by a majority of independent directors or a compensation committee that is composed entirely of independent directors, and (iii) the requirement that director nominees be selected or recommended to the board by a majority of independent directors or a nominating committee that is composed of entirely independent directors.

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

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

As a public company, we are incurring and will continue to incur significant legal, insurance, accounting and other expenses that we did not incur as a private company. In addition, our administrative staff is required to perform additional tasks and we are required to bear all of the internal and external costs of preparing and distributing periodic public reports in compliance with our obligations under the securities laws.

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

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

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, reduced disclosure obligations

regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an “emerging growth company.” We will remain an “emerging growth company” until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1 billion or more; (ii) December 31, 2017; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission.

A significant portion of our total outstanding shares of common stock is restricted from resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur in the future. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. Immediately after the completion of our IPO, we had 16,483,483 shares of common stock outstanding. Of these shares, 4,714,294 shares could be resold in the public market immediately and the remaining 11,769,189 shares are currently restricted under securities laws or as a result of lock-up agreements but will be able to be resold after the lock-up expires on April 8, 2013, subject to Rule 144. In addition, holders of an aggregate of 12,650,912 shares of our common stock, including shares underlying options and warrants of such holders, have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also have registered all 2,051,028 shares of common stock that we may issue under our equity compensation plans and as such they can be freely sold in the public market upon issuance and once vested, subject to the 180 day lock-up periods.

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

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

As of September 30, 2012, we had issued options to purchase 1,322,108 shares outstanding under our 2003 Stock Incentive Plan, as amended, and warrants to purchase 1,232,767 shares of our common stock. Furthermore, our 2012 Stock Incentive Plan, under which we may grant equity awards covering up to an additional 728,920 shares of our common stock (including 555,843 shares of common stock that were added from the 2003 Plan), was adopted and became effective upon the pricing of our IPO. On or about November 16, 2012, we will grant to our employees and directors (i) options to purchase 218,754 shares of our common stock and (ii) restricted stock units for 176,188 shares of our common stock, in each case, under our 2012 Plan. Sales of shares granted under our equity incentive plans or upon exercise of warrants may result in material dilution to our existing stockholders, which could cause our share price to fall.

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

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

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

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

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

- a decreased ability to issue additional securities or obtain additional financing in the future.

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

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

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

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

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

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

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

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

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

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

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

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

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

As of December 31, 2011 and September 30, 2012, we had federal net operating loss carryforwards, or NOLs, of $55.0 million and $68.5 million, respectively, which expire from 2024 through 2032. Our ability to utilize our NOLs may be limited under Section 382 of the Internal Revenue Code. The limitations apply if an ownership change, as defined by Section 382, occurs. Generally, an ownership change occurs when certain shareholders increase their aggregate ownership by more than 50 percentage points over their lowest ownership percentage in a testing period (typically three years). We have assessed whether one or more ownership changes as defined under Section 382 have occurred since our inception and have determined that there have been at least two such changes. Accordingly, although we believe that these ownership changes have not resulted in material limitations on our ability to use these NOLs, our ability to utilize the aforementioned carryforwards may be limited. Additionally, U.S. tax laws limit the time during which these carryforwards may be utilized against future taxes. As a result, we may not be able to take full advantage of these carryforwards for federal and state tax purposes. Future changes in stock ownership may also trigger an ownership change and, consequently, a Section 382 limitation.

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

Recent Sales of Unregistered Securities

Set forth below is information regarding securities sold by us during the three months ended September 30, 2012 that were not registered under the 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.

Issuances of securities

On August 9, 2012, we entered into a securities purchase agreement with an affiliated fund of OrbiMed Advisors LLC and Genextra S.p.A., pursuant to which the we agreed to issue up to an aggregate of 25,000,000 shares of Series C preferred stock at a price of $2.00 per share for gross proceeds of up to $50.0 million, or Series C financing. The securities purchase agreement for the Series C financing provided for the issuance of the Series C preferred stock in two tranches, consisting of 15,000,000 and 10,000,000 shares. On August 8, 2012, we amended and restated our Certificate of Incorporation in its entirety to increase the number of shares of preferred stock we are authorized to issue to 52,777,778 shares and designate 25,000,000 of such shares as Series C preferred stock. On August 9, 2012, we issued the first tranche of Series C preferred stock, which resulted in net proceeds of $29.7 million. The closing of the second tranche was only contemplated to occur if we did not complete an initial public offering of our common stock on or prior to August 2013.

Upon the completion of the IPO, all outstanding shares of our preferred stock were converted into 7,403,817 shares of common stock and the agreement to issue the second tranche of Series C preferred stock was nullified.

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 this transaction 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. All of the foregoing securities are deemed restricted securities for the purposes of the Securities Act.

Stock option and other equity awards

On July 31, 2012, we granted stock options to purchase 23,797 shares of common stock having an exercise price of $9.31 per share pursuant to our 2003 Plan to our non-employee directors as of January 1, 2012 for service during fiscal year 2012. The issuances of such options and the common stock issuable upon exercise of the options were exempt either pursuant to Rule 701 under the Securities Act, as a transaction pursuant to a compensatory benefit plan, or pursuant to Section 4(2) of the Securities Act, as a transaction by an issuer not involving a public offering.

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) Merrill Lynch, Pierce, Fenner & Smith Incorporated acted as book-running manager for the offering and as representatives of the underwriters. BMO Capital Markets, Needham & Company, Wedbush PacGrow Life Sciences, and ThinkEquity LLC acted as the co-managers for the offering. The offering commenced on October 10, 2012 and did not terminate until the sale of all of the shares offered.

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 directors or officers of ours or their associates or to persons owning 10 percent or more of our common stock or to any affiliates of ours.

We have invested the net proceeds from the offering in a variety of capital preservation investments, including short-term, investment grade, interest bearing instruments and U.S. government securities. There has been no material change in our planned use of the net proceeds from the offering as described in our final prospectus filed with the Securities and Exchange Commission pursuant to Rule 424(b) under the Securities Act on October 11, 2012.

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 26, 2012	By:	/s/ Mark Pruzanski, M.D. Mark Pruzanski President and Chief Executive Officer (principal executive officer)
Date: November 26, 2012	By:	/s/ Barbara Duncan Barbara Duncan Chief Financial Officer (principal financial and accounting officer)

Exhibit Index.

Exhibit Number	Description of Exhibit
3.1	Restated Certificate of Incorporation of Intercept Pharmaceuticals, Inc., effective as of October 16, 2012 (incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed on October 16, 2012).
3.2	Restated Bylaws of Intercept Pharmaceuticals, Inc., effective as of October 16, 2012 (incorporated by reference to Exhibit 3.2 to the Company's Form 8-K filed on October 16, 2012).
4.1	Form of Common Stock Certificate of Intercept Pharmaceuticals, Inc. (incorporated by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-8 (File No. 333-184810) filed on November 7, 2012).
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, 2012, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheet at December 31, 2011 and September 30, 2012 (unaudited), (ii) Condensed Consolidated Statements of Operations and Comprehensive Loss for the three month periods ended September 30, 2011 and 2012, the nine month periods ended September 30, 2011 and 2012 and the period from September 4, 2002 (inception) through September 30, 2012 (unaudited), (iii) Condensed Consolidated Statements of Cash Flows for the nine month periods ended September 30, 2011 and 2012 and for the period from September 4, 2002 (inception) to September 30, 2012 (unaudited) and (iv) Notes to Condensed Consolidated Financial Statements (unaudited) *

* XBRL Interactive Data File will be filed by amendment to this Form 10-Q within 30 days of the filing date of this Form 10-Q, as permitted by Rule 405(a)(2)(ii) of Regulation S-T.