INTERCEPT PHARMACEUTICALS INC
Form 424B4
October 11, 2012

Filed Pursuant to Rule 424(b)(4)
Registration No. 333-183706
Registration No. 333-184370

P R O S P E C T U S

5,000,000 Shares

Common Stock

This is Intercept Pharmaceuticals initial public offering. We are selling 5,000,000 shares of our common stock.

Currently, no public market exists for the shares. Our common stock has been approved for listing on the Nasdaq Global Market under the symbol ICPT.

We are an emerging growth company under federal securities laws and are subject to reduced public company disclosure standards. See Prospectus Summary Implications of Being an Emerging Growth Company.

Investing in our common stock involves risks that are described in the Risk Factors section beginning on page 10 of this prospectus.

	Per Share	Total
Public offering price	$15.00	$75,000,000
Underwriting discount	$1.05	$5,250,000
Proceeds, before expenses, to us	$13.95	$69,750,000

The underwriters may also exercise their option to purchase up to an additional 750,000 shares from us, at the public offering price, less the underwriting discount, for 30 days after the date of this prospectus.

Entities affiliated with one of our existing principal stockholders and directors and an entity affiliated with our director nominee have agreed to purchase an aggregate of $15.5 million in shares of our common stock in this offering at the initial public offering price.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The shares will be ready for delivery on or about October 16, 2012.

BofA Merrill Lynch

BMO Capital Markets

Needham & Company

Wedbush PacGrow Life Sciences

ThinkEquity LLC

The date of this prospectus is October 10, 2012.

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You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus. We are offering to sell, and seeking offers to buy, shares of common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of common stock.

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PROSPECTUS SUMMARY

This summary provides an overview of selected information contained elsewhere in this prospectus and does not contain all of the information you should consider before investing in our common stock. You should carefully read this prospectus and the registration statement of which this prospectus is a part in their entirety before investing in our common stock, including the information discussed under Risk Factors and our consolidated financial statements and notes thereto that appear elsewhere in this prospectus. Unless otherwise indicated herein, the terms we, our, us, or the Company refer to Intercept Pharmaceuticals, Inc.

Overview

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

Our Lead Product Candidate

Our lead product candidate, obeticholic acid, or OCA, is a bile acid analog and first-in-class agonist of the farnesoid X receptor, or FXR, which we believe has broad liver-protective properties. We are developing OCA initially for the second line treatment of primary biliary cirrhosis, or PBC. PBC is a chronic autoimmune liver disease that, if inadequately treated, may eventually lead to cirrhosis, liver failure and death. We are conducting a Phase 3 clinical trial of OCA in PBC, which we call the POISE trial, that we anticipate will serve as the basis for seeking regulatory approval in the United States and Europe. As of September 30, 2012, we had enrolled approximately two-thirds of the total number of patients targeted for our POISE trial, and we currently expect results from the trial to be available by mid-2014. OCA has received orphan drug designation in the United States and Europe for the treatment of PBC.

We own worldwide rights to OCA outside of Japan and China, where we have exclusively licensed the compound to Dainippon Sumitomo Pharma, or DSP, and granted it an option to exclusively license OCA in certain other Asian countries. Patents covering the composition of matter for OCA expire in 2022, before any patent term adjustments or patent term extensions. Our current plan is to commercialize OCA in the United States and Europe ourselves for the treatment of PBC by targeting a limited and focused group of specialist physicians.

The liver performs many essential functions that are crucial for survival, including the regulation of bile acid metabolism. A critical function of bile acids is to facilitate the absorption of dietary cholesterol and other nutrients by acting as natural detergent-like emulsifying agents in the intestine. In the past decade, we have learned that bile acids are also complex signaling molecules that integrate metabolic, immune and inflammatory pathways involved in the healthy functioning of various tissues and organs. The biological effects of bile acids are mediated through dedicated receptors such as FXR, which regulates bile acid synthesis and clearance from the liver, thereby preventing excessive bile acid build-up in the liver, which may be toxic. In addition, bile acid activation of FXR induces anti-fibrotic, anti-inflammatory and other mechanisms that are necessary for the normal regeneration of the liver. We believe this makes FXR an attractive drug target in a broad spectrum of chronic liver diseases. Similar FXR-mediated protective mechanisms in other organs exposed to bile acids also make it a potential target for the treatment of a number of intestinal, kidney and other diseases.

PBC is a rare liver disease that primarily results from autoimmune destruction of the bile ducts that transport bile acids out of the liver. The disease causes a toxic build-up of bile acids in the liver, resulting in progressive liver damage marked by chronic inflammation and fibrosis, or scarring. In response to the bile acid mediated toxicity seen in PBC, liver cells release alkaline phosphatase, or ALP, a liver enzyme that is a key biomarker of the disease pathology. Elevated blood levels of ALP are used as the primary means of diagnosis of PBC and are closely monitored in patients as the most important indicator of treatment response and prognosis.

The only approved drug for the treatment of PBC is ursodeoxycholic acid, which is available generically as ursodiol. Ursodiol is itself a bile acid that is present in small quantities in humans, and is the least

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detergent of the various types of bile acids that make up the bile pool. Its primary mechanism of action at therapeutic doses is to dilute more detergent bile acids, but it has no known pharmacological effects mediated by FXR or other bile acid receptors. Although ursodiol is the standard of care, studies have shown that up to 50% of PBC patients fail to respond adequately to treatment, meaning that they continue to be at significant risk of progressing to liver failure even with treatment. The options for end-stage PBC patients who fail to respond to ursodiol are limited, and include liver transplant, which is associated with significant complications and costs. Patients typically need to take approximately one gram of ursodiol daily in divided doses, which we believe presents a compliance challenge for some patients. Given this issue, coupled with ursodiol s limited efficacy in up to 50% of PBC patients, we believe that there is a significant unmet need for a novel second line therapy in PBC. We believe that OCA has the potential to provide significant benefits in the treatment of PBC, including efficacy, pharmacological activity and ease of use.

According to industry data, there are approximately 300,000 people with PBC in developed countries, of whom we believe approximately 60,000 have been diagnosed and are on ursodiol therapy. Based on this estimate, we believe there are up to 30,000 PBC patients who may currently be eligible for treatment with OCA. With increasing identification of PBC through routine liver function testing in primary care, we believe that there may be significantly more patients who will potentially be eligible for, and be interested in, receiving a new therapy if it becomes available on the market.

We have previously completed two randomized, placebo-controlled Phase 2 trials with OCA in PBC patients, one with OCA in combination with ursodiol and one with OCA as monotherapy. The results demonstrated that over a 12-week period single daily doses of OCA at the lowest dose of 10 milligrams (mg) met the primary endpoint in both Phase 2 trials, producing statistically significant reductions in ALP levels of greater than 20%. We consider reductions in ALP levels of greater than 10% to be a clinically meaningful improvement. Pruritus, or itching, a very common symptom in PBC patients, was the most common adverse event reported in our Phase 2 trials, with severity increasing with dose.

Our Phase 3 POISE trial has been designed to study the safety and efficacy of OCA in patients with an inadequate therapeutic response to ursodiol or who are unable to tolerate ursodiol. The primary endpoint of the 12-month double-blind portion of the POISE trial is the achievement of both an ALP level of less than 1.67 times upper limit normal, or ULN, and a minimum 15% reduction in ALP level from baseline, together with a normal bilirubin level, as compared to placebo. Patients with ALP and bilirubin levels within these thresholds have been shown in long-term studies to be at significantly lower risk of progressing to liver transplant and death.

We are advancing a once daily 10 mg dose of OCA in the POISE trial as our potential approvable dose. We recently completed an intention to treat analysis for the 10 mg dose groups in our two Phase 2 trials that was limited to those patients who would have met the POISE trial entry criteria. This analysis demonstrated that after 12 weeks of treatment approximately 40% to 45% of OCA-treated patients would have met the POISE trial primary endpoint, as compared to 5% to 9% of the placebo-treated patients. In addition, 80% of OCA-treated patients across our Phase 2 trials had a reduction in ALP levels of at least 10%, as compared to 13% of placebo-treated patients.

If the POISE trial is successful, we intend to submit a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, for approval of OCA for the treatment of PBC in the United States and a Marketing Authorization Application, or MAA, to the European Medicines Agency, or EMA, for approval in Europe. Based on written scientific advice from the EMA, we believe that the EMA will accept our current clinical program as the basis for considering approval of OCA for PBC. With respect to the FDA, we intend to request that the POISE trial primary endpoint be accepted as a basis for approval of OCA under the FDA s accelerated approval regulation that enables the use of a surrogate endpoint reasonably likely to predict clinical benefit. If the FDA agrees to consider the potential approval of OCA in accordance with its accelerated approval regulation based on the POISE trial results, we will

likely have to conduct a Phase 3 clinical outcomes trial to confirm the clinical benefit predicted by the biochemical therapeutic response. This Phase 3 clinical outcomes trial would have to be substantially underway at the time of the NDA submission and would be completed after accelerated approval. We are in discussions with the FDA about the details of such a clinical trial and are planning to initiate it as early as the second half of 2013.

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A number of published clinical studies have demonstrated that, as a measure of therapeutic response, lower levels of ALP, on its own or in conjunction with normal bilirubin levels, correlate with a significant reduction in adverse clinical outcomes such as liver transplant and death. We believe that one of the key factors in the FDA s acceptance of our POISE trial primary endpoint as a basis for approval will be the result of additional analysis of the already available PBC clinical outcomes data. We are sponsoring an independent study involving more than ten leading PBC centers in North America and Europe that are pooling their long-term patient data, anticipated to be from at least 4,000 patients, in order to further substantiate that our POISE trial primary endpoint is predictive of clinical benefit. We anticipate these results will be available in 2013 and will support what we believe is an emerging consensus among PBC opinion leaders concerning the clinical utility of our selected endpoint.

Additional Pipeline Opportunities Beyond OCA in PBC

In addition to PBC, we are pursuing other indications in our OCA development program, including portal hypertension, nonalcoholic steatohepatitis, or NASH, and bile acid diarrhea. The pipeline chart below shows the current stage of development of OCA for these indications, as well as the preclinical programs for our other product candidates.

* An agonist is a substance that binds to a receptor of a cell and triggers a response by that cell.

We are currently conducting an open label Phase 2a trial of OCA in patients with portal hypertension, and we anticipate receiving results from the 10 mg dose group of this trial by the end of 2012. There are currently no approved therapies for the treatment of portal hypertension, although beta blockers are commonly used to treat patients. In addition, OCA is currently being tested in a Phase 2b trial for the treatment of NASH, sponsored by the U.S. National Institute of Diabetes and Digestive and Kidney Diseases, or NIDDK, in collaboration with us. As of September 30, 2012, the NIDDK had enrolled approximately 90% of the total number of patients targeted for this trial. Based on the interim analysis that was completed in June 2012, the NIDDK decided to continue this Phase 2b trial and we anticipate that final results will be available in late 2014. There are currently no approved therapies for the treatment of NASH. In addition, investigators at the Imperial College of London initiated enrollment in July 2012 in an open label Phase 2a trial of OCA as a treatment for bile acid diarrhea.

By virtue of our patent portfolio and the proprietary knowhow of our employees and our collaborators at the University of Perugia, we believe that we hold a leading position in the bile acid chemistry therapeutic field. Through a longstanding exclusive collaboration with Professor Roberto Pellicciari, Ph.D., one of our co-founders, and certain scientists in the medicinal chemistry group at the University of Perugia, we have

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gained the capability to rationally design compounds that bind selectively and potently to FXR and other bile acid receptors. Starting with OCA, which was invented by Professor Pellicciari and, together with its underlying patents, was assigned to us under our agreements with him and the University of Perugia, our collaboration has resulted in a pipeline of bile acid analogs in addition to OCA, which target both FXR and a second dedicated bile acid receptor called TGR5, a target of interest for the treatment of type 2 diabetes and associated metabolic diseases. We intend to continue developing these and other product candidates as we advance our pipeline, in some cases subject to the procurement of additional funding or through strategic collaborations.

Our Strategy

Our strategy is to develop and commercialize novel therapeutics for patients with chronic liver and other diseases, beginning with OCA for the second line treatment of PBC and other follow-on indications that we believe are underserved by existing therapies. The key elements of our strategy are to:

complete the development of OCA for its lead indication, PBC;
obtain regulatory approval of OCA for the treatment of PBC in the United States, Europe and other countries;
commercialize OCA in the United States, Europe and other countries, initially for the treatment of PBC;
continue to develop OCA in other orphan and more prevalent liver and other diseases; and
advance the earlier stage product candidates in our pipeline.

We may enter into strategic collaborations to implement our strategy.

Risks Relating to Our Business

We are a development stage biopharmaceutical company, and our business and ability to execute our business strategy are subject to a number of risks of which you should be aware before you decide to buy our common stock. In particular, you should consider the following risks, which are discussed more fully in the section entitled Risk Factors :

we have never been profitable, have no products approved for commercial sale and to date have not generated any revenue from product sales;
we will require substantial additional funding beyond this contemplated offering to complete the development and commercialization of OCA and to continue to advance the development of our other product candidates, and such funding may not be available on acceptable terms or at all;
OCA and/or our other product candidates may not receive regulatory approval in a timely manner or at all;
the FDA may not agree to our proposed surrogate endpoint for accelerated approval of OCA for the treatment of PBC, in which case we would need to complete an additional Phase 3 trial in order to seek approval in the United States;
we may be subject to delays in our clinical trials, which could result in increased costs and delays or limit our ability to obtain regulatory approval for our product candidates;
because the results of earlier studies and clinical trials of our product candidates may not be predictive of future clinical trial results, our product candidates may not have favorable results in future clinical trials, which would delay or limit their future development;
we have never commercialized any of our product candidates and our products, even if approved, may not be accepted by healthcare providers or healthcare payors;
the failure of our collaborators to perform their obligations under our collaboration agreements may delay or otherwise harm the development and commercialization of our product candidates; and

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we may be unable to maintain and protect our intellectual property assets, which could impair the advancement of our pipeline and commercial opportunities.

Implications of Being an Emerging Growth Company

We qualify as an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced Management s Discussion and Analysis of Financial Condition and Results of Operations disclosure;

reduced disclosure about our executive compensation arrangements;

no non-binding advisory votes on executive compensation or golden parachute arrangements; and

exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is 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) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering; (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. We may choose to take advantage of some but not all of these exemptions. We have taken advantage of reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

Corporate Information

We were incorporated in the State of Delaware on September 4, 2002. Our principal executive offices are located at 18 Desbrosses Street, New York, NY 10013, and our telephone number is (646) 747-1000. We also have an office in San Diego, CA. Our website address is *www.interceptpharma.com*. The information contained on, or that can be accessed through, our website is not part of this prospectus.

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THE OFFERING

Common stock offered by us
5,000,000 shares

Common stock to be outstanding after this offering
15,733,483 shares

Option to purchase additional shares
We have granted the underwriters an option for a period of up to 30 days to purchase up to 750,000 additional shares of common stock at the initial public offering price.

Use of proceeds
We estimate that the net proceeds from this offering will be approximately $68.3 million, or approximately $78.7 million if the underwriters exercise their option to purchase additional shares in full, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use substantially all of the net proceeds from this offering to fund (i) the continued clinical development of OCA in PBC, including our Phase 3 POISE trial and other studies and work necessary for anticipated FDA and EMA filings; (ii) the continuation of the long-term safety extension portion of our POISE trial and the Phase 3 clinical outcomes trial after the anticipated FDA and EMA filings; (iii) certain pre-commercialization activities of OCA for PBC; (iv) further preclinical development work on INT-767 and, if warranted, Phase 1 clinical trials of INT-767; and (v) if warranted, initiation of a Phase 2 clinical trial for an additional indication for OCA, such as portal hypertension. Any remaining amounts will be used for general corporate purposes, general and administrative expenses, capital expenditures, working capital and prosecution and maintenance of our intellectual property. See Use of Proceeds for a more complete description of the intended use of proceeds from this offering.

Risk factors
You should read the Risk Factors section of this prospectus beginning on page 10 for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.

Nasdaq Global Market symbol
ICPT

Entities affiliated with one of our existing principal stockholders and directors and an entity affiliated with our director nominee have agreed to purchase an aggregate of $15.5 million in shares of our common stock in this offering at the initial public offering price. These shares will be subject to lock-up restrictions described in Shares Eligible for Future Sale.

The number of shares of common stock to be outstanding after this offering is based on an aggregate of 10,733,483 shares, consisting of (i) 3,329,666 shares of common stock outstanding on June 30, 2012, (ii) 4,807,674 shares of common stock into which all of our preferred stock outstanding as of June 30, 2012 will be converted upon the completion of this offering and (iii) 2,596,143 shares of common stock into which the shares of preferred stock issued on August 9, 2012 will be converted upon the completion of this offering. The number of shares of our common stock outstanding immediately after this offering excludes:

1,309,364 shares of common stock issuable upon exercise of outstanding options as of June 30, 2012, at a weighted average exercise price of $8.98 per share, of which 973,873 shares are vested as of such date;
23,794 shares of common stock issuable upon exercise of options granted on July 31, 2012 under our 2003 Stock Incentive Plan, as amended, or 2003 Plan, at an exercise price of $9.31 per share, to our non-employee directors as of January 1, 2012 for service during fiscal year 2012;

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728,920 shares of our common stock reserved for future issuance under our 2012 Equity Incentive Plan, or 2012 Plan, which became effective upon the pricing of this offering (including 555,843 shares of common stock that were added from the 2003 Plan, which terminated immediately upon the pricing of this offering so that no further awards may be granted under the 2003 Plan), of which:

options to purchase 207,505 shares of our common stock will be granted to our employees and directors under our 2012 Plan on the 31st day after the completion of this offering; and

restricted stock units for 173,592 shares of our common stock will be granted to our employees and directors under our 2012 Plan on the 31st day after the completion of this offering; and

1,232,767 shares of common stock issuable upon the exercise of warrants outstanding as of June 30, 2012, at a weighted average exercise price of $9.38 per share.

Except as otherwise indicated, all information in this prospectus:

gives effect to the conversion of all outstanding shares of our preferred stock into an aggregate of 7,403,817 shares of our common stock upon the completion of this offering, including the conversion of our Series A, Series B and Series C preferred stock into 2,403,837 shares, 2,403,837 shares and 2,596,143 shares of common stock, respectively;

reflects the 1-for-5.7778 reverse stock split of our common stock effected on September 26, 2012;

gives effect to our restated certificate of incorporation and our restated by-laws to be adopted in connection with the completion of this offering; and

assumes no exercise by the underwriters of their option to purchase additional shares of our common stock.

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SUMMARY CONSOLIDATED FINANCIAL DATA

The summary consolidated financial data presented below for the years ended December 31, 2010 and 2011 are derived from our audited consolidated financial statements included elsewhere in this prospectus. The summary consolidated financial data presented below for the six months ended June 30, 2011 and 2012, and for the period from inception (September 4, 2002) to June 30, 2012 (required to be included since we are a development stage company), are derived from our unaudited financial statements included elsewhere in this prospectus. The unaudited consolidated financial statements have been prepared on the same basis as our audited consolidated financial statements and include, in the opinion of management, all adjustments necessary for a fair presentation of the financial information set forth in those statements.

Our historical results are not necessarily indicative of future operating results. You should read this summary consolidated financial data in conjunction with the sections entitled Risk Factors, Capitalization, Selected Financial Data and Management s Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements and related notes, all included elsewhere in this prospectus.

	Years Ended December 31,		Six Months Ended June 30,		Period From September 4, 2002 (Inception) Through June 30, 2012
	2010	2011	2011	2012	
	(In thousands, except share and per share amounts)				
			(Unaudited)		(Unaudited)
Statement of Operations Data:					
Licensing revenues	$	$1,805	$405	$1,518	$3,323
Operating expenses:					
Research and development	12,710	11,426	4,751	8,078	63,330
General and administrative	3,644	4,210	2,020	2,003	26,424
Total operating expenses	16,354	15,636	6,771	10,081	89,754
Loss from operations	(16,354)	(13,831)	(6,366)	(8,563)	(86,431)
Total other income (expense), net	1,266	1,093	115	797	4,125
Net loss	$(15,088)	$(12,738)	$(6,251)	$(7,766)	$(82,306)
Dividend on preferred stock, not declared	(2,901)	(3,000)	(1,500)	(1,500)	(9,814)
Net loss attributable to common stockholders	$(17,989)	$(15,738)	$(7,751)	$(9,266)	$(92,120)
Net loss per share, basic and diluted	$(5.40)	$(4.73)	$(2.33)	$(2.78)	
Weighted average shares outstanding, basic and diluted	3,329,666	3,329,666	3,329,666	3,329,666	
Pro forma information[1]					
Pro forma net loss attributable to common stockholders		$(12,738)		$(7,766)	

Pro forma net loss per share, basic and diluted (unaudited)	$(1.19)	$(0.72)

(1) Pro forma net loss and pro forma net loss per share, basic and diluted have been calculated after giving effect to (i) the conversion of our preferred stock outstanding as of such dates into an aggregate of 4,807,674 shares of common stock upon the completion of this offering and (ii) the conversion of our shares of preferred stock issued on August 9, 2012 into an aggregate of 2,596,143 shares of common stock upon the completion of this offering. See *Unaudited Pro Forma Information* and *Net Loss per Share and Unaudited Pro Forma Net Loss per Share* in note 2 to our consolidated financial statements, which are included elsewhere in this prospectus.

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The following summary unaudited balance sheet data as of June 30, 2012 is presented:

- on an actual basis;
- on a pro forma basis after giving effect to (i) the conversion of our preferred stock outstanding as of such date into an aggregate of 4,807,674 shares of common stock upon the completion of this offering, (ii) the conversion of our shares of preferred stock issued on August 9, 2012 into an aggregate of 2,596,143 shares of common stock upon the completion of this offering, (iii) the receipt of $29.8 million of net proceeds from the issuance of preferred stock on August 9, 2012, and (iv) the reclassification of certain warrants with registration rights upon the completion of this offering from stockholders equity to warrant liability; and
- on a pro forma as adjusted basis to give further effect to our sale of 5,000,000 shares of common stock in this offering at the initial public offering price of $15.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The summary unaudited pro forma as adjusted balance sheet is for informational purposes only and does not purport to indicate balance sheet information as of any future date.

	As of June 30, 2012		
	Actual	Pro Forma	Pro Forma As Adjusted
	(In thousands) (Unaudited)		
Balance Sheet Data:			
Cash and cash equivalents	$ 9,947	$ 39,747	$ 107,997
Working capital	6,104	35,904	104,154
Total assets	12,145	41,945	110,195
Accounts payable, accrued expenses and other liabilities	3,578	3,578	3,578
Warrant liability	4,856	5,280	5,280
Deferred revenue	13,091	13,091	13,091
Common and preferred stock	31	11	16
Additional paid-in capital	72,895	102,292	170,537
Accumulated deficit during development stage	(82,306)	(82,306)	(82,306)
Total stockholders equity (deficit)	(9,380)	19,997	88,247

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RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the following risk factors, as well as the other information in this prospectus, including our financial statements and related notes, before deciding whether to invest in shares of our common stock. The occurrence of any of the adverse developments described in the following risk factors could materially and adversely harm our business, financial condition, results of operations or prospects. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment.

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, including net losses of $15.1 million and $12.7 million for the years ended December 31, 2010 and 2011, respectively, and we incurred a net loss of $7.8 million for the six months ended June 30, 2012. We had an accumulated deficit of $82.3 million as of June 30, 2012. Our working capital and cash and cash equivalents as of June 30, 2012 were $6.1 million and $9.9 million, respectively, and, after giving effect to the receipt of $29.8 million of net proceeds from the issuance of preferred stock on August 9, 2012, our working capital and cash equivalents as of June 30, 2012 would have been $35.9 million and $39.7 million, respectively.

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

We have never been profitable. Currently, we have no products approved forcommercial sale, and to date we have

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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.

We intend to use substantially all of the net proceeds from this offering to fund (i) the continued clinical development of OCA in PBC, including our Phase 3 POISE trial and other studies and work necessary for anticipated FDA and EMA filings; (ii) the continuation of the long-term safety extension portion of our POISE trial and the Phase 3 clinical outcomes trial after the anticipated FDA and EMA filings; (iii) certain pre-commercialization activities of OCA for PBC; (iv) further preclinical development work on INT-767 and, if warranted, potential Phase 1 clinical trials of INT-767; and (v) if warranted, initiation of a Phase 2 clinical trial for an additional indication for OCA, such as portal hypertension. Any remaining amounts will be used for general corporate purposes, general and administrative expenses, capital expenditures, working capital and prosecution and maintenance of our intellectual property. As such, the expected net proceeds from this offering 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 beyond the expected proceeds of this offering 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;

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;

We will require substantial additional funding, which may not be available tous on acceptable terms, or at all, and, if

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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. Upon the completion of this offering, 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, including $29.8 million of net proceeds received on August 9, 2012 upon the issuance of our Series C preferred stock, along with the net proceeds from this offering, to be sufficient to enable us to complete the commercialization of OCA, if approved, or to initiate any clinical trials or additional development work for any of our other product candidates, other than as described above. See also Use of Proceeds. 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:

We have a limited operating history and we expect a number of factors tocause our operating results to fluctuate on

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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, the results of any quarterly or annual periods 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

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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.

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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.

We may never reach an agreement with the FDA on a surrogate endpoint for the accelerated approval of OCA for t

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 this offering, together with existing cash and cash equivalents, including $29.8 million of net proceeds received on August 9, 2012 upon the issuance of our Series C preferred stock, 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 beyond the net

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proceeds of this offering. 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.

Delays in the commencement, enrollment and completion of clinical trialscould result in increased costs to us and d

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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

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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

Reimbursement decisions by third-party payors may have an adverse effect on pricing and market acceptance. If th

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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

If we market products in a manner that violates healthcare fraud and abuselaws, or if we violate government price r

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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.

If the FDA and EMA and other regulatory agencies do not approve the manufacturing facilities of our future contract

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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:

limitations or warnings contained in our product candidates FDA-approved labeling;

Even if approved, our product candidates may not achieve broad marketacceptance among physicians, patients an

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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.

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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.

If any of our current strategic collaborators fails to perform its obligations or terminates its agreement with us, the de

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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 beyond the net proceeds of this offering 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.

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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;

We face competition from other biotechnology and pharmaceutical companiesand our operating results will suffer if

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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

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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

We may not be able to manage our business effectively if we are unable toattract and retain key personnel and con

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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 will 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. As we begin operating as a public company following this offering, we will 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

Failure to build our finance infrastructure and improve our accounting systems and controls could impair our ability t

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of $1 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering; (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

We face potential product liability exposure, and if successful claims arebrought against us, we may incur substanti

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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.

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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 August 31, 2012, we were the owner of record of 45 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 12 pending U.S. and non-U.S. patent applications relating to OCA in these areas.

In addition, as of August 31, 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

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection. Our pat

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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.

We may infringe the intellectual property rights of others, which may preventor delay our product development effor

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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.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submis

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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

No public market for our common stock currently exists and an active trading market may not develop or be sustained following this offering.

Prior to this offering, there has been no public market for our common stock. An active trading market may not develop following the completion of this offering or, if developed, may not be sustained. Entities affiliated with one of our existing stockholders and directors and an entity affiliated with our director nominee have agreed to purchase an aggregate of $15.5 million in shares of our common stock in this offering at the initial public offering price. These purchases will reduce the available public float for our shares because these investors will be restricted from selling the shares under the lock-up agreements described in the Shares

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Eligible for Future Sale section of this prospectus. As a result, the liquidity of our common stock could be significantly reduced from what it would have been if these shares had been purchased by investors that were not affiliated with us. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. An inactive market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

Our share price may be volatile, which could subject us to securities class action litigation and prevent you from being able to sell your shares at or above the offering price.

The initial public offering price for our shares was determined by negotiations between us and the representatives of the underwriters and may not be indicative of prices that will prevail in the trading market. 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. If the market price of shares of our common stock after this offering does not exceed the initial public offering price, you may not realize any return on your investment in us and may lose some or all of your investment.

No public market for our common stock currently exists and an active tradingmarket may not develop or be sustaine

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

Genextra S.p.A., together with its affiliates, whom we refer to collectively as Genextra, is our largest stockholder. Upon the completion of this offering, Genextra will beneficially own shares representing approximately 48.6% of our common stock. Accordingly, Genextra will exert 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 after this offering, 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.

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 will consist of seven directors upon the completion of this offering, including two designated by Genextra, has the power to set the number of directors on our board from time to time. Lorenzo Tallarigo, M.D., the chief executive officer of Genextra, and Paolo Fundaro, the chief financial officer of Genextra, were elected to our board of directors as nominees of Genextra under the provisions of our third amended and restated stockholders agreement that will terminate upon the completion of this offering.

We have broad discretion in the use of net proceeds from this offering and may not use them effectively.

We intend to use substantially all of the net proceeds from this offering to fund (i) the continued clinical development of OCA in PBC, including our Phase 3 POISE trial and other studies and work necessary for anticipated FDA and EMA filings; (ii) the continuation of the long-term safety extension portion of our POISE trial and the Phase 3 clinical outcomes trial after the anticipated FDA and EMA filings; (iii) certain pre-commercialization activities of OCA for PBC; (iv) further preclinical development work on INT-767 and, if warranted, potential Phase 1 clinical trials of INT-767; and (v) if warranted, initiation of a Phase 2 clinical trial for an additional indication for OCA, such as portal hypertension. Any remaining amounts will be used for general corporate purposes, general and administrative expenses, capital expenditures, working capital and prosecution and maintenance of our intellectual property. Although we currently intend to use the net proceeds from this offering in such a manner, we will have broad discretion in the application of the net proceeds. Our failure to apply these funds effectively could affect our ability to continue to develop and commercialize our product candidates.

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

As a public company, we will incur significant legal, insurance, accounting and other expenses that we did not incur as a private company. In addition, our administrative staff will be required to perform additional tasks. For example, in anticipation of becoming a public company, we will need to adopt additional internal controls and disclosure controls and procedures, retain a transfer agent, adopt an insider trading policy and bear all of the internal and external costs of preparing and distributing periodic public reports in compliance with our obligations under the securities laws.

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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 this offering, we are increasing our directors and officers insurance coverage, which will increase our insurance cost. In the future, it will 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 will be able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies, which 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) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering; (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.

Purchasers in this offering will experience immediate and substantial dilution in the book value of their investment.

The initial public offering price is substantially higher than the net tangible book value per share of shares of our common stock based on the total value of our tangible assets less our total liabilities immediately following this offering. Therefore, if you purchase shares of our common stock in this offering, you will experience immediate and substantial dilution of $9.39 per share in the price you pay for shares of our common stock as compared to its pro forma as adjusted net tangible book value. To the extent outstanding options or warrants to purchase shares of

common stock that are in the money are exercised, there will be further dilution. For further information on this calculation, see Dilution elsewhere in this prospectus.

Purchasers in this offering will experience immediate and substantial dilutionin the book value of their investment.

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A significant portion of our total outstanding shares of common stock is restricted from immediate 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. After this offering, we will have 15,733,483 outstanding shares of common stock based on the number of shares outstanding as of August 31, 2012. Of these shares, 4,139,295 shares may be resold in the public market immediately and the remaining 11,594,188 shares are currently restricted under securities laws or as a result of lock-up agreements but will be able to be resold after this offering as described in the Shares Eligible for Future Sale section of this prospectus. Moreover, after this offering, holders of an aggregate of 12,650,912 shares of our common stock, including shares underlying options and warrants of such holders, will 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 intend to register all 2,062,078 shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance and once vested, subject to the 180 day lock-up periods under the lock-up agreements described in the Underwriting section of this prospectus.

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 June 30, 2012, we had issued options to purchase 1,309,364 shares outstanding under our 2003 Stock Incentive Plan, as amended, or 2003 Plan, and warrants to purchase 1,232,767 shares of our common stock. On July 31, 2012, we also granted options to purchase 23,794 shares of our common stock under the 2003 Plan to to our non-employee directors as of January 1, 2012 for service during fiscal year 2012. Furthermore, our 2012 Stock Incentive Plan, or 2012 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 this offering. On the 31st day after the completion of this offering, we will grant to our employees and directors (i) options to purchase 207,505 shares of our common stock and (ii) restricted stock units for 173,592 shares of our common stock, in each case, under our 2012 Plan. We plan to register the number of shares issuable upon outstanding awards and available for issuance under our 2003 Plan and 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 will depend on 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 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.

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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.

Our common stock has been approved for listing on the NASDAQ Global Market. In order to make a final determination of compliance with their listing criteria, NASDAQ may look to the first trading day s activity and, particularly, the last bid price on such day. In the event the trading price for our common stock drops below the NASDAQ Global Market s $4.00 minimum bid requirement, NASDAQ could rescind our initial listing approval. If that were to happen, the liquidity for our common stock would decrease. If we failed 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.

In addition, 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 that will be effective upon the completion of this offering, 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.

Some provisions of our charter documents and Delaware law may haveanti-takeover effects that could discourage a

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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 to be in effect upon the completion of this offering will limit 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 to be in effect upon the completion of this offering will 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 to be in effect upon the completion of this offering will provide 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 or plan to enter into indemnification agreements with each of our officers and directors and our director nominee, the form of which is attached as an exhibit to the registration statement of which this prospectus is a part.

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 plan to increase 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.

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

As of December 31, 2011 and June 30, 2012, we had federal net operating loss carryforwards, or NOLs, of $55.0 million and $63.9 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.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. All statements other than statements of historical facts contained in this prospectus, 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, could, estimate, expect, intend, may, plan, potential, predict, pr will, would 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;
our use of the net proceeds from this offering;
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 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 prospectus, particularly in the Risk Factors section, 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.

The forward-looking statements in this prospectus represent our views as of the date of this prospectus. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this prospectus.

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Industry and Market Data

This prospectus contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. We obtained the industry and market data in this prospectus from our own research as well as from industry and general publications, surveys and studies conducted by third parties. This data involves a number of assumptions and limitations and contains projections and estimates of the future performance of the industries in which we operate that are subject to a high degree of uncertainty. We caution you not to give undue weight to such projections, assumptions and estimates. Further, industry and general publications, studies and surveys generally state that they have been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe that these publications, studies and surveys are reliable, we have not independently verified the data contained in them. In addition, while we believe that the results and estimates from our internal research are reliable, such results and estimates have not been verified by any independent source.

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USE OF PROCEEDS

We estimate that our net proceeds from the sale of 5,000,000 shares of common stock in this offering will be approximately $68.3 million after deducting underwriting discounts and commissions and estimated offering expenses payable by us. If the option to purchase additional shares is exercised in full, we estimate that our net proceeds will be approximately $78.7 million.

The principal purposes of this offering are to obtain additional capital to support our operations, to create a public market for our common stock and to facilitate our future access to the public equity markets. We intend to use the net proceeds from this offering as follows:

approximately $17.0 million to fund the continued clinical development and other studies and work needed for the anticipated FDA and EMA filings for OCA as a treatment for PBC, as detailed below;
approximately $19.0 million to fund the continuation of the long-term safety extension portion of our POISE clinical trial and the Phase 3 clinical outcomes trial after the anticipated FDA and EMA filings;
approximately $10.0 million to fund certain pre-commercialization activities of OCA for PBC;
approximately $4.0 million to fund further preclinical development work on INT-767 and, if warranted, Phase 1 clinical trials of INT-767;
approximately $5.0 million to fund the initiation of a Phase 2 clinical trial for an additional indication for OCA, such as portal hypertension, if warranted; and
the remainder for general corporate purposes, general and administrative expenses, capital expenditures, working capital and prosecution and maintenance of our intellectual property.

We believe that the remaining clinical development and other studies and work needed for anticipated FDA and EMA filings for the approval of OCA as a treatment for PBC will require approximately $40.0 million. We believe that our existing cash and cash equivalents, including $29.8 million of net proceeds received on August 9, 2012 upon the issuance of our Series C preferred stock, along with the net proceeds from this offering, together with interest on cash balances, will be sufficient to fund our operating expenses and capital expenditure requirements through 2016 and fund the continued development of OCA through the following events:

the completion of our Phase 3 POISE trial;
initiation of the long-term safety extension portion of the POISE trial and continuation of the ongoing long-term safety extension portion of the Phase 2 monotherapy clinical trial;
initiation of a Phase 3 clinical outcomes trial to confirm clinical benefit of OCA in PBC;
two-year animal carcinogenicity studies in both rats and mice;
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;
manufacturing of clinical drug supply and materials necessary for the anticipated FDA and EMA filings;
the initiation of a Phase 2 clinical trial for an additional indication for OCA, such as portal hypertension, if warranted; and
the work required for assimilation, preparation and submission of the anticipated FDA and EMA filings.

The amount and timing of our actual expenditures will depend upon numerous factors, including the ongoing status and results of the POISE trial. Furthermore, we anticipate that we will need to secure additional funding for the further development of OCA for other indications and for the development of our other product candidates.

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Our expected use of net proceeds from this offering represents our current intentions based upon our present plans and business condition. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual use of net proceeds will vary depending on numerous factors, including our ability to obtain additional financing, the relative success and cost of our research, preclinical and clinical development programs, the amount and timing of additional revenues, if any, received from our collaborations with DSP and Servier and whether we are able to enter into future collaborations. As a result, management will have broad discretion in the application of the net proceeds, and investors will be relying on our judgment regarding the application of the net proceeds of this offering. In addition, we might decide to postpone or not pursue other clinical trials or preclinical activities if the net proceeds from this offering and the other sources of cash are less than expected.

Pending their use, we plan to invest the net proceeds from this offering in short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

DIVIDEND POLICY

We have never paid or declared any cash dividends on our common stock, and we do not anticipate paying any cash dividends on our common stock in the foreseeable future. We intend to retain all available funds and any future earnings to fund the development and expansion of our business. Any future determination to pay dividends will be at the discretion of our board of directors and will depend upon a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant.

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CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of June 30, 2012:

- on an actual basis;
- on a pro forma basis after giving effect to (i) the conversion of our preferred stock outstanding as of such date into an aggregate of 4,807,674 shares of common stock upon the completion of this offering, (ii) the conversion of our shares of preferred stock issued on August 9, 2012 into an aggregate of 2,596,143 shares of common stock upon the completion of this offering, (iii) the receipt of $29.8 million of net proceeds from the issuance of preferred stock on August 9, 2012, and (iv) the reclassification of certain warrants with registration rights upon the completion of this offering from stockholders equity to warrant liability; and
- on a pro forma as adjusted basis to give further effect to our issuance and sale of 5,000,000 shares of our common stock in this offering at the initial public offering price of $15.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this table together with Selected Financial Data, our financial statements and the related notes appearing at the end of this prospectus and the Management s Discussion and Analysis of Financial Condition and Results of Operations section of this prospectus.

	As of June 30, 2012		
	Actual	Pro Forma	Pro Forma as Adjusted
	(In thousands, except share amounts) (Unaudited)		
Cash and cash equivalents	$9,947	$39,747	$107,997
Warrant liability	4,856	5,280	5,280
Preferred stock, $0.001 par value; 27,777,778 shares authorized, issued and outstanding, actual; 52,777,778 shares authorized and no shares issued and outstanding, pro forma; and 5,000,000 shares authorized and no shares issued and outstanding, pro forma as adjusted	28		
Stockholders equity (deficit):			
Common stock, $0.001 par value; 57,000,000 shares authorized, 3,329,666 shares issued and outstanding, actual; 150,000,000 shares authorized and 10,733,483 shares issued and outstanding, pro forma; 25,000,000 shares authorized and 15,733,483 shares issued and outstanding, pro forma as adjusted	3	11	16
Additional paid-in capital	72,895	102,292	170,537
Accumulated deficit during development stage	(82,306)	(82,306)	(82,306)
Total stockholders equity (deficit)	(9,380)	19,997	88,247
Total capitalization	$(4,524)	$25,277	$93,527

The number of shares of common stock to be outstanding after this offering is based on an aggregate of 10,733,483 shares, consisting of (i) 3,329,666 shares of common stock outstanding on June 30, 2012, (ii) 4,807,674 shares of common stock into which all of our preferred stock outstanding as of June 30, 2012 will be converted upon the completion of this offering and (iii) 2,596,143 shares of common stock into which the shares of preferred stock issued on August 9, 2012 will be converted upon the completion of this offering. It does not include:

1,309,364 shares of common stock issuable upon exercise of outstanding options as of June 30, 2012, at a weighted average exercise price of $8.98 per share, of which 973,873 shares are vested as of such date;

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23,794 shares of common stock issuable upon exercise of options granted on July 31, 2012 under our 2003 Stock Incentive Plan, as amended, or 2003 Plan, at an exercise price of $9.31 per share, to our non-employee directors as of January 1, 2012 for service during fiscal year 2012;

728,920 shares of our common stock reserved for future issuance under our 2012 Equity Incentive Plan, or 2012 Plan, which became effective upon the pricing of this offering (including 555,843 shares of common stock that were added from the 2003 Plan, which terminated immediately upon the pricing of this offering so that no further awards may be granted under the 2003 Plan), of which:

options to purchase 207,505 shares of our common stock will be granted to our employees and directors under our 2012 Plan on the 31st day after the completion of this offering; and

restricted stock units for 173,592 shares of our common stock will be granted to our employees and directors under our 2012 Plan on the 31st day after the completion of this offering; and

1,232,767 shares of common stock issuable upon the exercise of warrants outstanding as of June 30, 2012, at a weighted average exercise price of $9.38 per share.

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DILUTION

If you invest in our common stock, your ownership interest will be diluted to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering. Dilution results from the fact that the initial public offering price per share is substantially in excess of the book value (deficit) per share attributable to the existing stockholders for the presently outstanding stock. As of June 30, 2012, our net tangible book value (deficit) was $(9.4) million, or $(2.82) per share of common stock. Net tangible book value (deficit) per share represents the amount of our total tangible assets less total liabilities, divided by 3,329,666, the number of shares of common stock outstanding on June 30, 2012.

Our pro forma net tangible book value (deficit) as of June 30, 2012 was $20.0 million, or $1.86 per share of common stock. Pro forma net tangible book value (deficit) per share represents the amount of our total tangible assets less our total liabilities, divided by the number of shares of our common stock outstanding, as of June 30, 2012, after giving effect to (i) the conversion of our preferred stock outstanding as of such dates into an aggregate of 4,807,674 shares of common stock upon the completion of this offering, (ii) the conversion of the shares of preferred stock issued on August 9, 2012 into an aggregate of 2,596,143 shares of common stock upon the completion of this offering, (iii) the receipt of $29.8 million of net proceeds from the issuance of preferred stock on August 9, 2012, and (iv) the reclassification of certain warrants with registration rights upon the completion of this offering from stockholders equity to warrant liability.

After giving effect to the sale of 5,000,000 shares of our common stock in this offering at the initial public offering price of $15.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of June 30, 2012 would have been $88.2 million, or $5.61 per share. This amount represents an immediate increase in pro forma as adjusted net tangible book value of $3.75 per share to our existing stockholders and an immediate dilution in pro forma as adjusted net tangible book value of approximately $9.39 per share to new investors purchasing shares of our common stock in this offering. We determine dilution by subtracting the pro forma as adjusted net tangible book value per share after the offering from the amount of cash that a new investor paid for a share of common stock.

The following table illustrates this dilution on a per share basis:

Initial public offering price per share		$ 15.00
Historical net tangible book value (deficit) per share as of June 30, 2012	$(2.82)	
Increase per share due to the conversion of all shares of preferred stock	1.94	
Decrease per share due to the reclassification of warrants with registration rights to liability	(0.04)	
Increase per share due to the issuance of Series C preferred stock	2.78	
Pro forma net tangible book value per share as of June 30, 2012	$1.86	
Increase per share attributable to new investors	$3.75	
Pro forma net tangible book value per share after the offering		5.61
Dilution per share to new investors		$ 9.39

If the underwriters exercise their option to purchase additional shares in full, the pro forma as adjusted net tangible book value per share after giving effect to the offering would be $5.99 per share. This represents an increase in pro forma as adjusted net tangible book value of $0.38 per share to existing stockholders and an increase in pro forma as adjusted net tangible book value of $0.38 per share to new investors.

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The following table summarizes, on a pro forma as adjusted basis as of June 30, 2012, the total number of shares purchased from us, the total consideration paid, or to be paid, and the average price per share paid, or to be paid, by existing stockholders and by new investors in this offering at the initial public offering price of $15.00 per share, before deducting underwriting discounts and commissions and estimated offering expenses payable by us. As the table shows, new investors purchasing shares in this offering will pay an average price per share substantially higher than our existing stockholders paid.

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percentage	Amount	Percentage	
Existing stockholders	10,733,483	68.22 %	$ 105,391,685	58.42 %	$ 9.82
New investors	5,000,000	31.78	75,000,000	41.58	$ 15.00
Total	15,733,483	100 %	$ 180,391,685	100 %	$ 11.47

The table above is based on (i) 3,329,666 shares of common stock outstanding on June 30, 2012, (ii) 4,807,674 shares of common stock into which all of our preferred stock outstanding as of June 30, 2012 will be converted upon the completion of this offering and (iii) 2,596,143 shares of common stock into which the shares of preferred stock issued on August 9, 2012 will be converted upon the completion of this offering.

The table above does not include:

1,309,364 shares of common stock issuable upon exercise of outstanding options as of June 30, 2012, at a weighted average exercise price of $8.98 per share, of which 973,873 shares are vested as of such date;
23,794 shares of common stock issuable upon exercise of options granted on July 31, 2012 under our 2003 Stock Incentive Plan, as amended, or 2003 Plan, at an exercise price of $9.31 per share, to our non-employee directors as of January 1, 2012 for service during fiscal year 2012;
728,920 shares of our common stock reserved for future issuance under our 2012 Equity Incentive Plan, or 2012 Plan, which became effective upon the pricing of this offering (including 555,843 shares of common stock that were added from the 2003 Plan, which terminated immediately upon the pricing of this offering so that no further awards may be granted under the 2003 Plan), of which:
options to purchase 207,505 shares of our common stock will be granted to our employees and directors under our 2012 Plan on the 31st day after the completion of this offering; and
restricted stock units for 173,592 shares of our common stock will be granted to our employees and directors under our 2012 Plan on the 31st day after the completion of this offering; and
1,232,767 shares of common stock issuable upon the exercise of warrants outstanding as of June 30, 2012, at a weighted average exercise price of $9.38 per share.

If the underwriters exercise their option to purchase additional shares in full, the following will occur:

the percentage of shares of our common stock held by existing stockholders will decrease to approximately 65.1% of the total number of shares of our common stock outstanding after this offering; and
the number of shares of our common stock held by new investors will increase to 5,750,000, or approximately 34.9% of the total number of shares of our common stock outstanding after this offering.

To the extent that outstanding options or warrants are exercised, you will experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities may result in further dilution to our stockholders.

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Entities affliated with one of our principal stockholders have agreed to purchase an aggregate of $5.0 million in shares of our common stock in this offering at the initial public offering price. The foregoing discussion and tables do not reflect any purchases by this existing principal stockholder or its affiliated entities. After giving effect to the purchase of shares in this offering by this existing stockholder or its affiliated entities at the initial public offering price of $15.00 per share, our existing stockholders will hold 70.3% (67.1% if the underwriters exercise their option to purchase additional shares in full) of our common stock outstanding after this offering based on (i) 3,329,666 shares of common stock outstanding on June 30, 2012, (ii) 4,807,674 shares of common stock into which all of our preferred stock outstanding as of June 30, 2012 will be converted upon the completion of this offering and (iii) 2,596,143 shares of common stock into which the shares of preferred stock issued on August 9, 2012 will be converted upon the completion of this offering; and the new investors purchasing the remaining shares in this offering will hold 29.7% (32.9% if the underwriters exercise their option to purchase additional shares in full) of our common stock outstanding after this offering.

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SELECTED FINANCIAL DATA

The following table sets forth our selected financial data for the periods and as of the dates indicated. You should read the following selected financial data in conjunction with our audited and unaudited financial statements and the related notes thereto included elsewhere in this prospectus and the Management s Discussion and Analysis of Financial Condition and Results of Operations section of this prospectus.

The statement of operations data for the years ended December 31, 2010 and 2011, and the balance sheet data as of December 31, 2010 and 2011, are derived from our audited financial statements included elsewhere in this prospectus.

The statement of operations data for the six months ended June 30, 2011 and 2012, and for the period from inception (September 4, 2002) to June 30, 2012 (required to be included since we are a development stage company) and the balance sheet data as of June 30, 2012, are derived from our unaudited financial statements and the related notes thereto included elsewhere in this prospectus. Our interim unaudited financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America, or GAAP, on the same basis as the annual audited financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments, necessary to present a fair statement of our financial position as of June 30, 2012 and the results of our operations for the six months ended June 30, 2011 and 2012 and for the period from inception (September 4, 2002) to June 30, 2012.

Our historical results are not necessarily indicative of the results that may be expected in the future and interim results are not necessarily indicative of results to be expected for any other period or the full year.

	Years Ended December 31,		Six Months Ended June 30,		Period From September 4, 2002 (Inception) Through June 30, 2012
	2010	2011	2011	2012	
	(In thousands, except share and per share amounts)				
			(Unaudited)		(Unaudited)
Statement of Operations Data:					
Licensing revenues	$	$1,805	$405	$1,518	$3,323
Operating expenses:					
Research and development	12,710	11,426	4,751	8,078	63,330
General and administrative	3,644	4,210	2,020	2,003	26,424
Total operating expenses	16,354	15,636	6,771	10,081	89,754
Loss from operations	(16,354)	(13,831)	(6,366)	(8,563)	(86,431)
Total other income, net	1,266	1,093	115	797	4,125
Net loss	$(15,088)	$(12,738)	$(6,251)	$(7,766)	$(82,306)
Dividend on preferred stock, not declared	(2,901)	(3,000)	(1,500)	(1,500)	(9,814)
Net loss attributable to common stockholders	$(17,989)	$(15,738)	$(7,751)	$(9,266)	$(92,120)
	$(5.40)	$(4.73)	$(2.33)	$(2.78)	

Net loss per share, basic and diluted				
Weighted average shares outstanding, basic and diluted	3,329,666	3,329,666	3,329,666	3,329,666

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	Years Ended December 31,		Six Months Ended June 30,		Period From September 4, 2002 (Inception) Through June 30, 2012
	2010	2011	2011	2012	
	(In thousands, except share and per share amounts)				
			(Unaudited)		(Unaudited)
Pro forma information[1]					
Pro forma net loss attributable to common stockholders	$ (12,738)		$ (7,766)		
Pro forma net loss per share, basic and diluted (unaudited)	$ (1.19)		$ (0.72)		

(1) Pro forma net loss and pro forma net loss per share, basic and diluted have been calculated after giving effect to (i) the conversion of our preferred stock outstanding as of such dates into an aggregate of 4,807,674 shares of common stock upon the completion of this offering and (ii) the conversion of our shares of preferred stock issued on August 9, 2012 into an aggregate of 2,596,143 shares of common stock upon the completion of this offering. See *Unaudited Pro Forma Information* and *Net Loss per Share and Unaudited Pro Forma Net Loss per Share* in note 2 to our consolidated financial statements, which are included elsewhere in this prospectus.

	December 31,		June 30,
	2010	2011	2012
	(In thousands)		
			(Unaudited)
Balance Sheet Data:			
Cash and cash equivalents	$ 15,424	$ 17,707	$ 9,947
Total assets	17,118	19,470	12,145
Accounts payable, accrued expenses, and other liabilities	1,587	1,504	3,578
Warrant liability	6,881	5,836	4,856
Deferred revenue		14,608	13,091
Common and preferred stock	31	31	31
Additional paid-in capital	70,268	72,134	72,895
Accumulated deficit during development stage	(61,803)	(74,540)	(82,306)
Total stockholders equity (deficit)	8,318	(2,560)	(9,380)

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MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with Selected Financial Data and our financial statements and the related notes appearing elsewhere in this prospectus. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled Risk Factors included elsewhere in this prospectus.

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 until June 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 $73.0 million and through the receipt of $16.4 million of up-front payments under our collaborative agreements.

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 we agreed to issue up to an aggregate of 25,000,000 shares of our Series C preferred stock at a price of $2.00 per share for gross proceeds of up to $50.0 million. The securities purchase agreement provides that the Series C preferred stock may be issued in two tranches consisting of 15,000,000 and 10,000,000 shares. The first tranche of Series C preferred stock was issued on August 9, 2012, and resulted in $29.8 million of net proceeds to us. The closing of the second tranche of Series C preferred stock will only occur if we do not complete an initial public offering of our common stock on or prior to the one year anniversary of the closing of the first tranche. All of our outstanding shares of Series C preferred stock will convert into 2,596,143 shares of our common stock upon the completion of this offering. The investors have been granted certain demand and piggyback registration rights in respect of their securities under our third amended and restated stockholders agreement.

We have incurred net losses in each year since our inception in 2002. Our net losses were approximately $15.1 million and $12.7 million for the years ended December 31, 2010 and 2011, respectively, and $6.3 million and $7.8 million for the six months ended June 30, 2011 and 2012, respectively. As of June 30, 2012, we had an accumulated deficit of approximately $82.3 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;

maintain, expand and protect our intellectual property portfolio;

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continue our research and development efforts;

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 this offering 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 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 Phase 3 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 Les Laboratories Servier and Institut de Recherches Servier, or collectively 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 (equivalent to approximately $135.0 million as of June 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 six months ended June 30, 2012, we recognized $3.3 million in license revenue for the relevant amortization of the two up-front payments. We expect to recognize as revenue an additional $0.9 million for the amortization of these payments through 2012 and do not expect to receive any milestone payments during 2012 related to these agreements. The Servier up-front payment is expected to be fully amortized in the third quarter of 2012. 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.

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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 June 30, 2012, we have incurred approximately $63.3 million in research and development expenses. We plan to increase our research and development expenses for the foreseeable future as we continue the development of OCA for the treatment of PBC and other indications and to further advance the development of our other product candidates, subject to the availability of additional funding.

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

	Years Ended, December 31,		Six Months Ended, June 30,	
	2010	2011	2011	2012
	(In thousands)			
			(Unaudited)	
Direct research and development expense by program:				
OCA	$ 8,001	$ 8,056	$ 3,033	$ 5,922
INT-777	2,234	195	312	13
Total direct research and development expense	10,235	8,251	3,345	5,935
Personnel costs	2,078	2,750	1,180	1,830
Indirect research and development expense	397	425	226	313
Total research and development expense	$ 12,710	$ 11,426	$ 4,751	$ 8,078

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;

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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 the Phase 3 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, a Phase 3 clinical trial in patients with PBC, 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 August 31, 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 is expected to occur in 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 through preclinical development and, if warranted, Phase 1 clinical trials and INT-777 through potential collaborations with third parties, over the next several years.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for employees in executive, operational, finance and human resources functions. 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

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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 Income (Expense), Net

Interest income consists of interest earned on our cash and cash equivalents. We expect our interest income to increase following the completion of this offering as we invest the net proceeds from this offering pending their use in our operations.

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

Mark-to-Market Warrant Revaluation Income (Expense)

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 are currently classified in equity, contain provisions that require the shares of common stock underlying such warrants to be registered upon an initial public offering. Upon completion of this offering, we will reclassify these warrants as liabilities and record warrant revaluation income (expense) in the statement of operations. 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.

Critical Accounting Policies and Estimates

Our management s discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which we have prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of these consolidated financial statements requires us 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, as well as the reported revenues and expenses during the reporting periods. We evaluate these estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in note 2 to our consolidated financial statements appearing elsewhere in this prospectus, we believe that the following accounting policies are the most critical for fully understanding and evaluating our financial condition and results of operations.

Revenue Recognition

We recognize revenue when the following criteria are met: persuasive evidence that an arrangement exists, services have been rendered, the price is fixed or determinable and collectability is reasonably assured.

We have entered into collaboration agreements with DSP and Servier. The terms of these agreements include nonrefundable up-front licensing fees, in addition to potential milestone payments and royalties on any future product sales developed by the collaborators under our licenses. We assess these multiple elements in order to determine whether particular components of the arrangement represent separate units of accounting.

We recognize up-front license payments as revenue upon delivery of the license only if the license has stand-alone value. The underlying performance obligations are accounted for separately as the obligations are

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fulfilled. If the license is considered as not having stand-alone value, the arrangement is accounted for as a single unit of accounting and the license payments and payments for performance obligations are recognized as revenue over the estimated period of when the performance obligations are performed.

Whenever we determine that an arrangement should be accounted for as a single unit of accounting, we determine the period over which the performance obligations will be performed and revenue will be recognized. If we cannot reasonably estimate the timing and the level of effort to complete our performance obligations under the arrangement, then we recognize revenue under the arrangement on a straight-line basis over the period that we expect to complete our performance obligations.

Our collaboration agreements also provide for potential milestone payments to us, none of which have been received to date. Revenues from milestone payments, if they are non-refundable and considered substantive, are recognized upon successful accomplishment of the milestones. If milestones are not considered substantive, milestone payments are initially deferred and recognized over the remaining performance obligation.

To date, we have not received any royalty payments and accordingly have not recognized any related revenue. We will recognize royalty revenue upon the sale of the related products, provided we have no remaining performance obligations under the arrangement.

We record deferred revenue when payments are received in advance of the culmination of the earnings process. This revenue is recognized in future periods when the applicable revenue recognition criteria have been met.

Valuation of Stock-Based Compensation and Warrant Liability

Stock-Based Compensation

We record the fair value of stock options issued to employees as of the grant date as compensation expense. We recognize compensation expense over the requisite service period, which is the vesting period. For non-employees, we also record stock options at their fair value as of the grant date. We then periodically re-measure the awards to reflect the current fair value at each reporting period until the non-employee completes the performance obligation or the date on which a performance commitment is reached. Expense is recognized over the related service period.

Stock-based compensation expense includes stock options granted to employees and non-employees and has been reported in our statements of operations as follows:

	Years Ended December 31,		Six Months Ended June 30,	
	2010	2011	2011	2012
	(In thousands)			
			(Unaudited)	
Research and development	$ 648	$ 472	$ 341	$ 289
General and administrative	1,045	1,394	411	472
Total	$ 1,693	$ 1,866	$ 752	$ 761

We calculate the fair value of stock-based compensation awards using the Black-Scholes option-pricing model. The Black-Scholes option-pricing model requires the use of subjective assumptions, including stock price volatility, the expected life of stock options, risk free interest rate and the fair value of the underlying common stock on the date of

grant. Our key assumptions are:

We do not have sufficient history to estimate the volatility of our common stock price. We calculate expected volatility based on reported data for selected reasonably similar publicly traded companies for which the historical information is available. For the purpose of identifying peer companies, we consider characteristics such as industry, length of trading history, similar vesting terms and in-the-money option status. We plan to continue to use the guideline peer group volatility information until the historical volatility of our common stock is relevant to measure expected volatility for future option grants.

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The assumed dividend yield is based on our expectation of not paying dividends for the foreseeable future. We determine the average expected life of stock options based on the simplified method in accordance with the Securities and Exchange Commission Staff Accounting Bulletin Nos. 107 and 110, as our shares are not publicly traded. We expect to use the simplified method until we have sufficient historical exercise data to provide a reasonable basis upon which to estimate expected term.

We determine the risk-free interest rate by reference to implied yields available from U.S. Treasury securities with a remaining term equal to the expected life assumed at the date of grant.

We estimate forfeitures based on our historical analysis of actual stock option forfeitures.

The assumptions used in the Black-Scholes option-pricing model for the years ended December 31, 2010 and 2011 are set forth below:

	Years Ended December 31,			
	2010		2011	
Volatility	112	115%	107	115%
Expected term (in years)	5.6	5.7	5.0	6.0
Risk-free interest rate	1.6	1.7%	1.1	1.4%
Expected dividend yield		%		%
Stock price	$8.67		$8.67	

The following table presents the grant dates, number of underlying shares and related exercise prices of stock options granted to employees and consultants from January 1, 2010 through August 31, 2012, as well as the estimated fair value of the underlying common stock at each grant date.

Grant Date	Number of Shares	Exercise Price and Fair Value Per Share	Aggregate Intrinsic Value (In thousands)
8/16/2010	427,060	$ 8.67	
9/6/2010	28,990	$ 8.67	
10/13/2011	214,961	$ 8.67	
12/15/2011	6,057	$ 8.67	
7/31/2012	23,794	$ 9.31	

The estimated fair value of common stock per share in the table above represents the determination by our board of directors of the fair value of our common stock as of each date of grant, taking into consideration various objective and subjective factors, including the conclusions of valuations of our common stock, as discussed below.

The intrinsic value of all outstanding vested and unvested options as of June 30, 2012, based on the initial public offering price per share of $15.00, and the exercise price of the outstanding options are as follows:

	Number of Options	Intrinsic Value
Unvested	335,466	$ 2,093,020
Vested	973,873	$ 5,795,691

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Due to the absence of an active market for our common stock, the fair value of our common stock for purposes of determining the exercise price for stock option grants was determined by our board of directors, with the assistance and upon the recommendation of management, in good faith, based on a number of objective and subjective factors consistent with the methodologies outlined in the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, or the Practice Aid, including:

the prices at which we most recently sold our preferred stock and the rights, preferences and privileges of the preferred stock as compared to those of our common stock, including the liquidation preferences of the preferred stock;

our results of operations, financial position and the status of our research and development efforts, including the status of clinical trials for OCA and our specific regulatory status and interactions with regulatory authorities;

the likelihood of achieving a liquidity event for the holders of our common stock and stock options, such as an initial public offering, or IPO, given prevailing market conditions, or a strategic merger or sale of our company, or an M&A transaction;

the material risks related to our business;

achievement of enterprise milestones, including the results of clinical trials and our entry into or termination of collaboration and license agreements;

the market performance of publicly traded companies in the life sciences and biotechnology sectors, and recently completed mergers and acquisitions of companies comparable to us;

external market conditions affecting the life sciences and biotechnology industry sectors; and

the valuation prepared by an independent third-party consultant performed as of March 31, 2010 and July 31, 2012.

We relied, in part, upon a valuation performed by an independent third party firm as of March 31, 2010 in determining the fair value of our common stock for purposes of establishing stock option exercise prices and for utilization in the Black-Scholes option-pricing model for calculating stock compensation expense and the value of warrants that are classified as liabilities. We then performed our own update to this valuation as of September 30, 2011 and June 30, 2012, using the same valuation methodologies used by the independent third party, and relied, in part, upon an update to the valuation as of July 31, 2012 from the same independent third party firm that performed the 2010 valuation.

Each of these valuations utilized the same approach in estimating enterprise value, which was a combination of a market-based approach, an income-based approach and a liquidation approach. Utilizing these three different approaches, as described in more detail below, a total of eight enterprise values were considered at each valuation date.

Under the market-based approach, the valuations considered the enterprise values of comparable biotechnology companies in a similar stage of development as ours, based on market data from recent IPOs and M&A transactions. The valuations were based on two different potential enterprise values for each of the IPO and M&A scenarios, depending on our assumed expected date of the IPO or M&A transaction, as we believed that it was reasonable to assume that a transaction at a later date would result in a higher valuation due to anticipated continued progress in our business. This resulted in four estimated enterprise values at each valuation date (two for the IPO scenario and two for the M&A scenario). For the 2010 valuation, we assumed that an IPO would be completed in either mid-2011 or mid-2012 and established the enterprise values for the IPO scenario based upon the market-based approach as described above. For the September 2011 valuation, since we had passed the mid-2011 date without completing an IPO, we revised our assumptions about the expected date of an IPO. We further assessed and made adjustments to the dates used in the June 2012 and July 2012 valuations based on the circumstances at the time and maintained consistent enterprise values for each of the IPO scenarios in the various valuations. We made similar revisions in our assumptions about the expected timing of an M&A transaction by rolling forward the expected dates from the 2010 valuation and

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maintained constant the estimated enterprise values for a nearer term M&A transaction, given certain developments impacting our business during 2011 and 2012, as described below, but increased the estimated enterprise values for a longer-term M&A transaction from the 2010 valuation, given our expectations about our improved prospects in the longer term, as described below. The estimated enterprise values in the M&A scenarios were also based upon the market-based approach as described above. The estimated enterprise value in the longer-term M&A scenario was significantly greater than the values in the IPO scenarios because the market values for comparable companies completing an M&A transaction were significantly greater than comparable companies completing an IPO. The estimated enterprise value for the longer-term M&A scenario was also significantly greater than the values under the income-based approach for the continuing operation scenario discussed below.

Under the income-based approach, the valuations were based on a discounted cash flow, or DCF, analysis to estimate enterprise value under three different scenarios depending on various development and commercialization scenarios. As with any DCF analysis, we made assumptions around the timing and amount of future revenues and operating expenses, among other factors, as well as assumptions about taxes, working capital requirements, and, most significantly, the discount rate to be applied in the DCF analysis. Our assumptions reflected the current development status of OCA and our expectations about future clinical development and potential commercialization scenarios. For subsequent valuation dates in 2011 and 2012, we updated these assumptions based on developments in our business since the prior valuation date, as described below, which resulted in overall net positive, but immaterial, increases to the previously estimated enterprise values from each prior valuation date, with the size of the increases generally tied to the length of time since the prior valuation date. The estimated enterprise values in the various DCF scenarios were generally consistent with the estimated values in the IPO and near-term M&A scenarios for each valuation date. As discussed above, the enterprise value in the longer-term M&A scenario was assumed to be significantly higher than the near-term scenario because we assumed that we would make continued progress in our business prior to a longer-term M&A transaction.

Finally, for the liquidation approach, the valuations estimated an enterprise value based on potential proceeds available to stockholders upon a liquidation of our company, based on current cash, assets and liabilities and the assumed proceeds from the sale of our assets. For subsequent valuation dates in 2011 and 2012, we updated these financial metrics and assumed sale proceeds based on changes in our financial position and expected proceeds from the sale of our assets, which resulted in both positive and negative changes to the previously estimated enterprise values, although the value available to be distributed to common stockholders remained zero at each valuation date given the accumulated liquidation preferences of our preferred stock.

Once we estimated the enterprise values at each date, the determination of the fair value of our common stock required the allocation of these enterprise values using one of the approaches outlined in the Practice Aid, because we have multiple classes of capital stock. We relied on the probability-weighted expected return method, or PWERM, which models a company s common stock value based on potential future liquidity events and applies probabilities to each scenario. These future liquidity events are then discounted to present value and, after applying the relevant probability for each potential event, result in a single probability-weighted equity value of the common stock of a company.

For our valuations, we used the scenarios described above to generate the eight different enterprise values for our company. In determining the value of the common stock in the IPO and M&A scenarios, we assumed that the preferred stock then outstanding would be converted into common stock. This was due to the fact that the assumed enterprise values in the M&A scenarios would yield a return to holders of preferred stock that was greater than the liquidation value of the preferred stock and the assumed enterprise values in the IPO scenarios would have resulted in the automatic conversion of the preferred stock into common stock in accordance with our certificate of incorporation or we assumed that we would obtain requisite consent from the preferred stockholders to convert their shares into common stock in an IPO. In allocating value to our common stock in the continuing operations and liquidation

scenarios, we first allocated to our then outstanding shares of preferred stock the greater of the liquidation preference of the preferred stock and the

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amount that would have been payable had all such shares of preferred stock been converted to common stock immediately prior to such event, as required by our certificate of incorporation, and then allocated any remaining value to our common stock.

The resulting implied per share value of our common stock was $8.67 per share at both March 31, 2010 and September 30, 2011, $8.96 at June 30, 2012 and $9.30 at July 31, 2012. The probability weightings utilized in the PWERM analysis took into consideration, among other things, the actual and forecast quality of data from the completed and yet to be completed OCA clinical trials, respectively, our assessment of the overall development program that would be required for anticipated FDA and EMA filings to obtain marketing approval, as well as general prevailing market conditions. In each valuation, we assessed probabilities of an overall positive scenario (25%-35% probability), an overall mixed scenario (50%-60% probability) and an overall negative scenario (15% probability).

The tables below summarize the probability assessment of the described event in each of these scenarios.

	March 2010			September 2011		
Event	Positive Scenario	Mixed Scenario	Negative Scenario	Positive Scenario	Mixed Scenario	Negative Scenario
Strategic merger or sale of our company	15%	0 %	0 %	30%	0 %	0 %
Initial public offering	30%	15 %	0 %	15%	15 %	0 %
Continuing operations in various development and commercialization scenarios	55%	85 %	65 %	55%	85 %	65 %
Failure or dissolution of our company with no value to common stockholders	0 %	0 %	35 %	0 %	0 %	35 %

	June 2012			July 2012		
Event	Positive Scenario	Mixed Scenario	Negative Scenario	Positive Scenario	Mixed Scenario	Negative Scenario
Strategic merger or sale of our company	15%	0 %	0 %	15%	0 %	0 %
Initial public offering	40%	40 %	0 %	50%	35 %	0 %
Continuing operations in various development and commercialization scenarios	45%	60 %	65 %	35%	65 %	65 %
Failure or dissolution of our company with no value to common stockholders	0 %	0 %	35 %	0 %	0 %	35 %

The probability weightings assigned to the respective exit scenarios were primarily based on consideration of the status of our OCA development program, research programs, various regulatory interactions in the United States and Europe, industry clinical success rates, our expected near-term and long-term funding requirements, and an assessment of the then financing and overall biotechnology industry environments at the time the valuations were performed. In all scenarios, an overall discount rate of 25% and an additional discount for lack of marketability of up to 20% was applied at each valuation date. We also considered the rights, preferences and privileges of the preferred stock as compared to those of our common stock, including the liquidation preferences of the preferred stock. Our preferred stockholders have various rights that give them greater control and influence over future liquidity, financing and other decisions relating to our company than the holders of our common stock.

Except as otherwise described below, for the periods from June 30, 2011 to October 13, 2011; October 13, 2011 to December 15, 2011; December 15, 2011 to December 31, 2011; and December 31, 2011 to June 30, 2012, there were numerous changes in our underlying business and, therefore, in the assumptions utilized in arriving at the eight

estimated enterprise valuations at each valuation date and in the assumptions utilized in the PWERM analysis. However, as noted above, the estimated enterprise values did not change significantly from period to period and, taken together, the changes to the estimated enterprise values were offset by the changes in our assumptions in the PWERM analysis, and, as a result, there was no material change in our estimate of the fair value of our common stock.

The absence of any such material change in the fair value of our common stock is due to the fact that while, on the one hand, we (a) were making progress during these periods in our development program for OCA, including the planning of our Phase 3 program for OCA as a treatment for PBC and the initiation of the POISE trial, and (b) entered into the DSP and Servier collaborations described above, which would have the

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effect of increasing the estimated fair value of our common stock, on the other hand, (i) we did not receive the clarity that we were seeking from the FDA regarding whether the POISE trial would be sufficient and appropriate for accelerated approval of OCA and we also determined that we may be required to conduct a larger and more expensive confirmatory clinical outcomes trial than we had been anticipating; (ii) European market conditions continued to steadily decline with an increased risk of downward product pricing and reimbursement pressure across various European countries; and (iii) dynamics in the U.S. market for financing and partnering deteriorated for private development stage biopharmaceutical companies such as ours, all of which had the effect of decreasing the estimated fair value of our common stock. We believe that these positive and negative factors generally offset each other, resulting in a steady estimate of the fair value of our common stock in the absence of an arm s-length transaction or updated independent valuation indicating otherwise during the period.

To review the specific circumstances at the time of each successive valuation, in March 2010, we had just completed a $25 million Series B preferred stock financing and had recently successfully completed our Phase 2 clinical trial for OCA in PBC. Based upon an analysis of then current market conditions, together with the projections of management and the board of directors regarding future development timelines for our product candidates, we determined the probabilities of the different scenarios and events as reflected in the table above.

We re-evaluated the assumptions used and the resulting estimated enterprise values in our valuation analysis at the September 2011 valuation date. We considered the deteriorating market conditions for life science company IPOs and interactions with regulatory authorities about our proposed NDA and MAA program, which resulted in several material changes to our previously contemplated program, including our belief that we may be required to conduct a larger and more expensive confirmatory clinical outcomes trial. We rolled forward the timelines under the IPO and M&A transaction scenarios, but also increased the estimated enterprise value under the longer-term M&A scenario given that such a transaction was now projected to occur further in the future. Under the DCF analysis, we extended the timeline under which we expected to receive revenues but also revised other assumptions, resulting in net positive, but immaterial, increases in estimated enterprise values compared to the 2010 valuation. In addition, we slightly revised the probability assessments in the PWERM analysis to lower the probability of an IPO from 30% to 15% and increased the probability of a strategic merger or sale of our company from 15% to 30%. Since our valuation model had previously incorporated the potential for a licensing deal for OCA in Japan as well as the potential for a licensing deal for our TGR5 program, our entry into the DSP and Servier collaborations in March 2011 and August 2011, respectively, did not have an offsetting effect on the negative developments described above.

With regard to the June 2012 valuation date, based at the time on improving market conditions for life science company IPOs, our holding an organizational meeting and commencement of preparations in May 2012 for an IPO, the initial confidential submission of a draft registration statement on Form S-1 for our IPO in June 2012, our declining cash reserves, the initiation of the Phase 3 POISE trial and the continuation of the FLINT trial, along with our negotiations with several parties regarding a private financing, which increased our confidence in completing an IPO and continuing our clinical development activities, we shortened the timelines for an expected IPO. We also updated the various assumptions under the DCF analysis, resulting in net positive, but immaterial, increases in estimated enterprise values. In addition, based on the factors described above, we determined to increase the probability of the IPO in the PWERM analysis in both the positive and mixed scenario from 15% to 40%, with offsetting reductions in the strategic merger or sale of our company in a positive scenario by 15% and reductions in the probabilities of continuing operations from 55% to 45% in the positive scenario and from 85% to 60% in the mixed scenario.

With regard to the July 2012 valuation date, based upon the increased likelihood of completing the potential Series C preferred stock financing that would provide the company with near- and longer-term funding if a successful IPO could not be achieved, we re-evaluated our assumptions used in the June 30, 2012 valuation, resulting in no material

changes to the base assumptions. However, we determined (i) to further increase the IPO probability in the PWERM analysis in a positive scenario by 10% to a 50% probability, with an offsetting decrease in the probability of the continuing operations scenario, and (ii) to decrease the IPO probability in a mixed scenario by 5%, with a corresponding increase to the continuing operations scenario, reflecting the fact that an IPO would not be undertaken if it was not attractive.

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Management made significant judgments and estimates underlying the determination of these inputs to the valuations at each time point. These judgments and estimates were based on assumptions regarding our future performance, including the regulatory status of our programs; the attractiveness of completing an IPO at different time points; the potential value of a strategic merger or sale at different time points; and the timing and probability of continuing to successfully progress our various product candidates toward commercialization (our continued operations scenarios) under differing scenarios, as well as determinations of the appropriate valuation methods. If different assumptions had been applied in the valuations, our stock-based compensation expense, warrant liability remeasurement, net loss and net loss per share could have been significantly different. While the assumptions used represent management s informed estimates based on all available information at each time point, these estimates involve inherent uncertainties and the application of management s judgment.

Stock Option Grants on August 16, 2010 and September 6, 2010

Our board of directors granted stock options on August 16, 2010 and September 6, 2010, each having an exercise price of $8.67 per share, which our board of directors determined to be equal to the fair value of our common stock on each date of grant. The exercise price per share determined by our board of directors was supported by an independent third party valuation as of March 31, 2010. The specific facts and circumstances considered by our board of directors for the March 31, 2010 valuation included the following:

in January 2010, we sold 13,888,889 shares of our Series B preferred stock and a warrant to purchase 865,381 shares of our common stock for $25.0 million in aggregate gross proceeds. We assessed the value of the warrant at approximately $5.2 million based upon a Black-Scholes option-pricing model, and thus the implied per share value of the Series B preferred stock, on an as-converted basis was $8.26 per share, and

the regulatory status of our programs, the general market conditions for private company financings for development stage companies such as ours and the other items noted above.

The probability weightings, discussed above and listed in the table, assigned to the respective exit scenarios were primarily based on consideration of the factors described above. The resulting value, which represented the estimated fair value of our common stock as of March 31, 2010, was $8.67 per share.

In addition to the objective and subjective factors listed above, our board of directors also considered input from management and the valuation as of March 31, 2010. After considering the regulatory uncertainty faced by our development program for OCA together with certain countervailing factors, our board of directors determined that there was no change in the fair value of our common stock between March 31, 2010 and the dates of the stock option grants, August 16, 2010 and September 6, 2010, respectively.

Stock Option Grants on October 13, 2011 and December 15, 2011

Our board of directors granted stock options on October 13, 2011 and December 15, 2011, each having an exercise price of $8.67 per share, which our board of directors determined to be equal to the fair value of our common stock on each date of grant. We performed an update to the March 31, 2010 valuation as of September 30, 2011. The specific facts and circumstances considered by our board of directors for the September 30, 2011 valuation included the following: the regulatory status of our programs, the general market conditions for private company financings for development stage companies such as ours, the impact of our collaboration agreements with DSP and Servier and the other general items noted above. Among these factors, the board of directors considered the offsetting effects on the fair value of our common stock due to our new collaborative arrangements, on the one hand, and the continuing lack of regulatory clarity around our development program for OCA in the United States, on the other hand.

The probability weightings assigned to the respective exit scenarios, discussed above and detailed in the table, were primarily based on consideration of the factors described above. The resulting value, which represented the estimated fair value of our common stock as of September 30, 2011, was $8.67 per share.

Our board of directors determined that there was no change in the fair value of our common stock during the period between September 30, 2011 and December 15, 2011 because no significant event or other circumstances had occurred between those dates that would indicate a change had occurred in the fair value of our common stock.

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Stock Option Grants on July 31, 2012

Our board of directors granted stock options on July 31, 2012, each having an exercise price of $9.30 per share, which our board of directors determined to be equal to the fair value of our common stock on the date of grant.

The exercise price per share determined by our board of directors was supported by an independent third party valuation analysis as of July 31, 2012 using the approaches discussed above to incorporate eight different enterprise values and the PWERM methodology to allocate these values to the common stock. The specific facts and circumstances considered by our board of directors for the July 31, 2012 valuation included the following: (i) the clinical development progress of OCA, including the initiation of the POISE trial and the continuation of the FLINT and PESTO trials, as well as risks and costs associated with these trials, (ii) the regulatory status of our programs, including communications received from the FDA concerning our Phase 3 program for OCA as a treatment for PBC, (iii) the general fluctuating market conditions for private company financings for development stage companies such as ours, including our negotiations relating to the potential of a Series C private placement followed by an IPO, (iv) the anticipated terms of our Series C preferred stock, including certain control rights and liquidation preferences anticipated to be granted to the holders of our Series C preferred stock, which would result in a higher implied value for our Series C preferred stock as compared to our common stock, (v) the general deteriorating market conditions in European markets for health care payor reimbursement of approved products, and (vi) other general factors consistent with the Practice Aid, such as risk factors faced by our company, the investments made in our company and the experience and competence of our management team. The probability weightings assigned to the respective exit scenarios, discussed above and detailed in the table, were primarily based on consideration of these factors.

Estimated Offering Price

On September 26, 2012, we and the underwriters determined the estimated price range for this offering. The midpoint of the estimated range was $14.00 per share. In comparison, our estimate of the fair value of our common stock was $9.31 per share as of July 31, 2012. We note that, as is typical in initial public offerings, the estimated price range for this offering was not derived using a formal determination of fair value, but was determined based upon discussions between us and the underwriters. Among the factors considered in setting the estimated range were prevailing market conditions and estimates of our business potential, as described above. In addition to this difference in purpose and methodology, we believe that the difference in value reflected between the midpoint of the estimated range and the board of directors determination of the fair value of our common stock on July 31, 2012 was primarily the result of the following factors:

The July 31, 2012 valuation used a probability weighting of 50% that the IPO would occur in a positive scenario. However, the estimated IPO price range, which was determined based upon discussions between us and the underwriters, necessarily assumes that the initial public offering has occurred, that a public market for our common stock has been created and that all outstanding shares of our preferred stock have been converted into common stock in connection with the initial public offering, and therefore excludes any discount for lack of marketability of our common stock, which was factored in the July 31, 2012 valuation. As such, the previously used private company valuation methodology is no longer applicable.

Our preferred stock currently has substantial economic rights and preferences superior to our common stock. The midpoint of the estimated price range assumed the conversion of our preferred stock upon the completion of this offering and the corresponding elimination of such economic rights and preferences, resulting in an increased common stock valuation, which more than offsets the dilutive impact of the conversion of our preferred stock to common stock.

The proceeds of a successful initial public offering would substantially strengthen our balance sheet by increasing our cash resources. Additionally, the completion of this offering would provide us with access to the public company debt

and equity markets. These projected improvements in our financial position influenced the increased common stock valuation indicated by the midpoint of the estimated price range.

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Common Stock Warrant Liability

Some of our outstanding warrants to purchase shares of our common stock have anti-dilution provisions (commonly referred to as down round provisions) which cause the instruments to be deemed not to be indexed to our common stock and as such are recorded as a liability and remeasured each reporting period using the Black-Scholes option-pricing model. Furthermore, certain warrants that do not have these down-round provisions, and are currently classified in equity, contain provisions that require the shares of common stock underlying such warrants to be registered following an initial public offering. Upon completion of this offering, we will reclassify these warrants as liabilities and record warrant revaluation income (expense) in the statement of operations. These 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 are determined by us using a Black-Scholes option-pricing model, which, under our facts and circumstances, approximate, in all material respects, the values determined using a binomial valuation model. The non-cash changes in the fair value of the warrants are recorded as other income or expense. We expect that the value of the warrants will fluctuate significantly from period to period.

The Black-Scholes option-pricing model and the bionomial valuation model require the use of 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. The fair value of the underlying common stock is determined as discussed above under Stock-Based Compensation. We will continue to adjust the fair values of the warrants at each period end for any changes in fair value 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. Our warrant liability is expected to fluctuate based on the assumptions used in our valuation model.

JOBS Act

On April 5, 2012, the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, was enacted. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, or the Securities Act, for complying with new or revised accounting standards. In other words, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, as an emerging growth company, we intend to rely on certain of these exemptions, including without limitation, (i) providing an auditor s attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the PCAOB regarding mandatory audit firm rotation or a supplement to the auditor s report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. 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) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering; (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.

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Results of Operations

Comparison of the Six Months Ended June 30, 2011 and the Six Months Ended June 30, 2012

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

	Six Months Ended June 30,		Dollar Change	% Change
	2011	2012		
	(In thousands) (Unaudited)			
Licensing revenue	$ 405	$ 1,518	$ 1,113	*
Operating expenses:				
Research and development	4,751	8,078	3,327	70.0 %
General and administrative	2,020	2,003	(17)	(0.8)%
Loss from operations	(6,366)	(8,563)	(2,197)	34.5 %
Interest income, net	21	10	(11)	(52.0)%
Foreign currency loss in liquidation		(192)	(192)	*
Warrant revaluation income (expense)	94	979	885	*
Net loss	$ (6,251)	$ (7,766)	$ (1,515)	24.2 %

* Not meaningful or not calculable.

Licensing Revenue

Licensing revenue was $405,000 and $1,518,000 for the six months ended June 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 $4.8 million and $8.1 million for the six months ended June 30, 2011 and 2012, respectively, representing an increase of $3.3 million, or 70.0%. This increase in research and development expense primarily reflects:

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;

increased direct development expense for the initiation of our Phase 3 POISE trial of approximately $1.5 million;

increased direct development expense for the initiation of our two-year animal carcinogenicity studies in two species of approximately $700,000;

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 $650,000 and associated overhead of approximately $75,000; and

a partial offset primarily by decreases in costs related to (i) research expenses for our earlier stage pipeline assets of $300,000, and (ii) 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 TRG5 program, which was previously paid by us and is now funded through our collaboration with Servier.

General and Administrative Expenses

General and administrative expenses were $2.0 million in both the six months ended June 30, 2011 and 2012.

Interest Income, Net

Interest income, net was $21,000 and $10,000 for the six months ended June 30, 2011 and 2012, respectively.

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Warrant Revaluation Income (Expense)

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 gains of $94,000 and $979,000 for the six months ended June 30, 2011 and 2012, respectively. These gains are primarily due to the reduction in value of the warrants due to declines in their estimated life and changes in volatility of the shares of common stock underlying the warrants. For the six months ended June 30, 2012, these gains were offset to a lesser extent by the increase in fair value of the common stock underlying the warrants.

Comparison of the Year Ended December 31, 2010 and the Year Ended December 31, 2011

The following table summarizes our results of operations for the years ended December 31, 2010 and 2011, together with the changes in those items in dollars and as a percentage:

	Years Ended December 31,		Dollar Change	% Change
	2010	2011		
	(In thousands)			
Licensing revenue	$	$ 1,805	$ 1,805	*
Operating expenses:				
Research and development	12,710	11,426	(1,284)	(10.1)%
General and administrative	3,644	4,210	566	15.5 %
Loss from operations	(16,354)	(13,831)	2,523	15.4 %
Interest income, net	105	48	(57)	(54.3)%
Warrant revaluation income (expense)	672	1,045	373	55.5 %
Qualified therapeutic development project	489		(489)	*
Net loss	$ (15,088)	$ (12,738)	2,350	15.6 %

* Not meaningful or not calculable.

Licensing Revenue

For the year ended December 31, 2011, we recorded a total of $1.8 million of licensing revenue, consisting of $1.2 million and $600,000 from the amortization of the up-front payments from the collaboration agreements entered into during 2011 with DSP and Servier, respectively. We had no revenue prior to 2011.

Research and Development Expenses

Research and development expenses were $12.7 million and $11.4 million for the years ended December 31, 2010 and 2011, respectively. The net decline in research and development expenses of $1.3 million, or 10.1%, was primarily due to:

reduced direct research and development expense relating to INT-777 of approximately $2.0 million;
reduced direct research and development expense 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

Interest Income, Net

collaboration with Servier, of approximately $1.2 million;
reduced direct research and development expense with respect to the completion of our Phase 2 trials for OCA of approximately $600,000;
reduced direct research and development expense related to payments to the NIDDK for the FLINT trial of $250,000;
increased direct expenditures associated with the preparation for the initiation of the POISE trial of approximately $1.2 million;

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increase in personnel in our development team to manage the increased activities around our development program for OCA, resulting in increased compensation expense of approximately $400,000;

increased expenditures for direct research and development expense relating to our Phase 2 clinical trial for portal hypertension of approximately $400,000;

increased costs to manufacture our clinical trial supplies of approximately $500,000; and

increased costs associated with market research of $200,000.

General and Administrative Expenses

General and administrative expenses were $3.6 million and $4.2 million for the years ended December 31, 2010 and 2011, respectively. The increase in general and administrative expenses of $565,000, or 15.5%, was mainly due to an increase in stock-based compensation costs for options granted to our employees and legal costs associated with the DSP and Servier collaboration agreements.

Interest Income, Net

Interest income, net was $105,000 and $48,000 for the years ended December 31, 2010 and 2011, respectively. The decrease of $57,000, or 54%, was driven by lower average cash balances.

Warrant Revaluation Income (Expense)

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 gains of $700,000 and $1.0 million for the years ended December 31, 2010 and 2011, respectively. These gains are 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.

QTDP Grant

In 2010, we were awarded $489,000 under the federal Qualifying Therapeutic Discovery Grant Program, or QTDP, in support of our development of OCA and INT-777. The QTDP was included in the healthcare reform legislation, and established a one-time pool of $1 billion for grants to small biotechnology companies developing novel therapeutics which show potential to result in new therapies that either treat areas of unmet medical need, or prevent, detect or treat chronic or acute diseases and conditions; reduce long-term health care costs in the United States; or significantly advance the goal of curing cancer within a the 30-year period.

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 June 30, 2012, we had an accumulated deficit of $82.3 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 June 30, 2012, we have funded our operations principally with $73.0 million (net of issuance costs of $2.4 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 June 30, 2012, we had cash and cash equivalents of approximately $9.9 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Currently, our funds are held in cash and money market bank accounts.

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 we agreed to issue up to an aggregate of 25,000,000

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shares of our Series C preferred stock at a price of $2.00 per share for gross proceeds of up to $50.0 million. The securities purchase agreement provides that the Series C preferred stock may be issued in two tranches consisting of 15,000,000 and 10,000,000 shares. The first tranche of Series C preferred stock was issued on August 9, 2012, and resulted in $29.8 million of net proceeds to us. The closing of the second tranche of Series C preferred stock will only occur if we do not complete an initial public offering of our common stock on or prior to the one year anniversary of the closing of the first tranche. All of our outstanding shares of Series C preferred stock will convert into 2,596,143 shares of our common stock upon the completion of this offering. The investors have been granted certain demand and piggyback registration rights in respect of their securities under our third amended and restated stockholders agreement.

After giving effect to the $29.8 million in net proceeds we received in the Series C preferred stock financing, our cash and cash equivalents as of June 30, 2012 would have been $39.7 million.

The gross proceeds we have received from the issuance and sale of common stock, convertible notes, preferred stock and warrants, as of August 31, 2012, are as follows:

Securities Issued	Year		Number of Shares	Common Stock Underlying Warrants	Gross Proceeds
Common stock, convertible notes and warrants	2002	2009	3,329,666	504,697	$25,391,685
Series A preferred stock* and warrant	2008		2,403,837	108,169	25,000,000
Series B preferred stock* and warrant	2010		2,403,837	865,381	25,000,000
Series C preferred stock*	2012		2,596,143		30,000,000
Total			10,733,483	1,478,247	$105,391,685

* On an as-converted basis.

Cash Flows

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

	Years Ended, December 31,		Six Months Ended, June 30,	
	2010	2011	2011	2012
	(In thousands)			
			(Unaudited)	
Net cash provided by (used in):				
Operating activities	$(13,658)	$2,606	$9,318	$(7,768)
Investing activities	58	(66)	(75)	97
Financing activities	24,618	(250)	(107)	(82)
Effect of exchange rate changes	(29)	(6)	36	(7)
Net increase (decrease) in cash and cash equivalents	$10,989	$2,284	$9,172	$(7,760)

Operating Activities. Net cash used in operating activities of $13.7 million during the year ended December 31, 2010

was primarily a result of our $15.1 million net loss, offset by the add-back of non-cash expenses of $1.7 million for stock-based compensation and $480,000 for depreciation and warrant liability revaluation income of $672,000. Net cash provided by operating activities of $2.6 million during the year ended December 31, 2011 was primarily a result of $16.4 million in up-front payments from our licensing and collaboration agreements with DSP and Servier, $14.6 million of which was classified as deferred revenue as described in note 3 to our financial statements included elsewhere in this prospectus. The cash payments from the collaboration agreements and the classification of those payments as deferred revenue led to an overall net increase in operating assets of $13.9 million, to which non-cash items of $1.9 million for stock-based compensation, $410,000 for depreciation and $217,000 for a loss on the sale of assets in connection with the

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liquidation of our Italian subsidiary were added. These positive additions to cash flow were offset against our $12.7 million net loss and an additional $1.0 million decrease in assets due to the revaluation of our warrant liabilities.

Net cash provided by operating activities of $9.3 million during the six months ended June 30, 2011 was primarily a result of the $15.0 million up-front payment from our licensing and collaboration agreement with DSP, which was classified as deferred revenue as described in note 3 to our financial statements included elsewhere in this prospectus. The cash payment and the classification of this payment as deferred revenue led to an overall net increase in operating assets of $15.0 million to which non-cash items of $752,000 for stock-based compensation and $161,000 for depreciation were added. These positive additions to cash flow were offset against our $6.3 million net loss and an additional $94,000 decrease in assets due to the revaluation of our warrant liabilities. Net cash used in operating activities of $7.8 million during the six months ended June 30, 2012 was primarily a result of our $7.8 million loss, offset by the add-back of non-cash items of $761,000 for stock-based compensation, depreciation of $154,000, warrant liability revaluation income of $979,000 and net changes in our operating assets and liabilities of $130,000. The net change in our operating assets and liabilities include an increase in prepaid expenses and other current assets of $686,000, increases in accounts payable, accrued expense and other current liabilities of $2.1 million and a decrease in deferred revenue of $1.5 million. The decrease in deferred revenue is due to the recognition of a portion of the up-front license payment from our license agreement with DSP.

Investing Activities. Net cash used in investing activities during the periods presented primarily reflected our use of cash to purchase equipment. Cash provided by short-term investments was partially offset by sales of short-term investments.

Financing Activities. Net cash provided by financing activities in the year ended December 31, 2010 consisted primarily of approximately $24.0 million of net proceeds from the sale of Series B preferred stock and warrants to purchase common stock issued in 2010, offset by capital lease payments. Net cash used in financing activities in the year ended December 31, 2011 consisted primarily of capital lease payments.

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

Based upon our current operating plan, we believe that the net proceeds from this offering, 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 intend to devote the net proceeds from this offering to fund our Phase 3 POISE trial and our planned clinical trials and preclinical studies and other work needed to submit applications for OCA for the treatment of PBC for regulatory approval in the United States and Europe; to fund the continuation of the long-term safety extension portion of our POISE clinical trial and the Phase 3 clinical outcomes trial after the anticipated FDA and EMA filings; to fund further preclinical development work on INT-767 and, if warranted, potential Phase 1 clinical trials of INT-767; to fund the initiation of a Phase 2

clinical trial for an additional indication for OCA, such as portal hypertension if warranted; and for general corporate purposes, general and administrative expenses, capital expenditures, working capital and prosecution and maintenance of our intellectual property. See Use of Proceeds for a more detailed discussion. We will need to obtain additional financing to fund future clinical trials of OCA in additional indications, including portal hypertension, NASH and bile acid diarrhea, or for progressing INT-767 beyond Phase 1 clinical trials and INT-777. We have based our estimates on assumptions that may prove to be wrong, and we may use our available capital resources

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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.

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Contractual Obligations and Commitments

The following table summarizes our significant contractual obligations and commercial commitments at December 31, 2011 and the effects such obligations are expected to have on our liquidity and cash flows in future periods:

	Total	Less than 1 year	1 3 years	3 5 years	More than 5 years
	(In thousands)				
Operating lease	$ 838	$ 294	$ 544		
Capital lease	82	82			
Purchase obligations	3,568	1,964	1,604		
Total	$ 4,488	$ 2,340	$ 2,148		

In June 2007, we entered into a capital lease agreement for research and development equipment utilized in our research facility. The term of the lease was for five years, required monthly payments of $22,275, bore interest at a rate of 4.66% per year and matured on May 31, 2012. We lease general and administrative office space in New York, New York and San Diego, California pursuant to operating leases that expire in 2013 and 2014, respectively. We have two contracts that require us to make specified payments necessary to perform our obligations under the Servier collaboration agreement. The amounts payable under these contracts through the initial term of the Servier agreement is included in the table above even though we expect to receive reimbursement from Servier for these costs.

During 2011, we entered into an agreement with WIL Research Laboratories, LLC, or WIL, to perform certain research and laboratory services for animal studies and have agreed to pay WIL a total of $4.0 million in periodic installment payments. These amounts are included in table above.

We are a party to license agreements with universities and other third parties, as well as patent assignment agreements, under which we have obtained rights to patents, patent applications and know-how. We have employment agreements with certain employees which require the funding of specific levels of payments, if certain events, such as a change in control or termination without cause, occur. We enter into contracts in the normal course of business with CROs for clinical trials and clinical supply manufacturing and with vendors for preclinical research studies and other services and products for operating purposes, which generally provide for termination within 30 days of notice, and therefore are cancelable contracts and not included in the table of contractual obligations and commitments.

Under our contract with the NIDDK, we made a milestone payment of $1.0 million in June 2012 and will be required to make an additional $1.25 million payment within 60 days of full enrollment of the FLINT trial, which is expected to occur in 2012. As of December 31, 2011, we were unable to estimate the timing or likelihood of the NIDDK achieving the milestones and, therefore, the amounts are not included in the table above. As of June 30, 2012, we have recorded expenses totaling $2.0 million and expect to record an additional $250,000 in 2012 for a total of $2.25 million in 2012 relating to these milestone obligations.

Under our agreement with DSP, we are required to use our commercially reasonable efforts to develop OCA outside of the territories in which DSP has a license under the agreement. As these amounts are not quantifiable, they are not included in the table above.

Under our agreement with Servier, we are obligated to conduct and are conducting a research program to identify and optimize compounds that meet certain specified criteria sufficient for further development by Servier. We are obligated under the agreement to provide Servier with a specified number of full time equivalent employees for the

research program and Servier has agreed to reimburse us on a quarterly basis for the associated costs up to a set maximum amount per year. Servier has agreed to pay for the development costs we or Servier incur in conducting certain preclinical trials and clinical trials with respect to any compound that meets specified criteria. We have agreed to reimburse Servier for a certain percentage of the development costs incurred by Servier if we enter into a partnership agreement, or commence development or commercialization activities on our own, with respect to a compound in the United States. Servier may credit a portion of any such reimbursable development costs against any milestone or royalty payments due and

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payable by Servier under the agreement until all such reimbursable amounts are repaid. In addition, if we enter into a partnership agreement with respect to a compound developed under the agreement solely in Japan, we and Servier have agreed to enter into good faith negotiations regarding the terms and conditions applicable to the reimbursement of development costs. These amounts are not included in the table above because they are not quantifiable or because they are reimbursable under the agreement.

Our commitments as of December 31, 2011 under our sponsored research agreement with the University of Perugia and Professor Roberto Pellicciari, our two consulting agreements with Professor Pellicciari and our research and development agreement with TES Pharma Srl are reflected in the table above. However, all the commitments as of December 31, 2011 under our consulting agreement with Professor Pellicciari and our agreement with TES Pharma Srl, in each case, for the compounds related to the Servier agreement were covered by the reimbursement provisions under our agreement with Servier.

Net Operating Losses

As of December 31, 2011 and June 30, 2012, we had federal net operating loss carryforwards, or NOLs, of $55.0 million and $63.9 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.

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 Securities and Exchange Commission rules.

Recent Accounting Pronouncements

In June 2011, the FASB issued authoritative guidance related to the Presentation of Comprehensive Income. This standard eliminates the current option to report other comprehensive income and its components in the statement of changes in equity. The new GAAP requirements were effective for public entities for fiscal years beginning after December 15, 2011 and interim periods within that year, with early adoption permitted. As we had historically presented a single Statement of Operation and Comprehensive Loss, the adoption of this standard did not impact our financial statements.

In May 2011, the FASB issued amended guidance on fair value measurements. This newly issued accounting standard clarifies the application of certain existing fair value measurement guidance and expands the disclosures for fair value measurements that are estimated using significant unobservable (Level 3) inputs. This accounting standard was effective on a prospective basis for annual and interim reporting periods beginning on or after December 15, 2011.

The adoption of this standard has not had a material impact on our financial position or results of operations.

Basic and Diluted Net Loss Attributable to Common Stockholders per Common Share

Our Series A, B and C preferred stock represent participating securities. However, since we operate at a loss, and losses are not allocated to the preferred stock, the two class method does not affect our calculation of earnings per share. We had a net loss for all periods presented; accordingly, the inclusion of common stock options and warrants would be anti-dilutive.

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Dilutive common stock equivalents would include the dilutive effect of convertible securities, common stock options and warrants for common stock. Potentially dilutive common stock equivalents totaled approximately 7,888,566 shares and 8,309,074 shares for the years ended December 31, 2010 and 2011, respectively. Potentially dilutive common stock equivalents were excluded from the diluted earnings per share denominator for all periods because of their anti-dilutive effect. Therefore, the weighted average shares used to calculate both basic and diluted earnings per share are the same.

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.

Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10.0% change in interest rates would not have a material effect on the fair market value of our portfolio. Accordingly, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our investment portfolio.

We do not believe that our cash, cash equivalents and available-for-sale investments have significant risk of default or illiquidity. While we believe our cash and cash equivalents and certificates of deposits do not contain excessive risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits.

We contract with CROs and investigational sites in Europe, Canada and Australia. We are therefore subject to fluctuations in foreign currency rates in connection with these agreements. We do not hedge our foreign currency exchange rate risk.

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations during 2010 or 2011 or through the six months ended June 30, 2012.

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BUSINESS

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.

Our lead product candidate, obeticholic acid, or OCA, is a bile acid analog, a chemical substance that has a structure based on a naturally occurring human bile acid. OCA is a first-in-class product candidate that selectively binds to and induces activity in the farnesoid X receptor, or FXR, which we believe has broad liver-protective properties. We are developing OCA initially for primary biliary cirrhosis, or PBC, as a second line treatment for patients who have an inadequate response to or who are unable to tolerate standard of care therapy and therefore need additional treatment. PBC is a chronic autoimmune liver disease that, if inadequately treated, may eventually lead to cirrhosis, liver failure and death. We are conducting a Phase 3 clinical trial of OCA in PBC, which we call the POISE trial, that we anticipate will serve as the basis for seeking regulatory approval in the United States and Europe. As of September 30, 2012, we had enrolled approximately two-thirds of the total number of patients targeted for our POISE trial, and we currently expect results from the trial to be available by mid-2014. OCA has received orphan drug designation in the United States and Europe for the treatment of PBC. We own worldwide rights to OCA outside of Japan and China, where we have exclusively licensed the compound to Dainippon Sumitomo Pharma, or DSP, and granted it an option to exclusively license OCA in certain other Asian countries.

The liver performs many essential functions that are crucial for survival, including the regulation of bile acid metabolism. A critical function of bile acids is to facilitate the absorption of dietary cholesterol and other nutrients by acting as natural detergent-like emulsifying agents in the intestine. In the past decade, we have learned that bile acids are also complex signaling molecules that integrate metabolic, immune and inflammatory pathways involved in the healthy functioning of various tissues and organs. The biological effects of bile acids are mediated through dedicated receptors such as FXR, which regulates bile acid synthesis and clearance from the liver, thereby preventing excessive bile acid build-up in the liver, which may be toxic. In addition, bile acid activation of FXR induces anti-fibrotic, anti-inflammatory and other mechanisms that are necessary for the normal regeneration of the liver. We believe this makes FXR an attractive drug target in a broad spectrum of chronic liver diseases. Similar FXR-mediated protective mechanisms in other organs exposed to bile acids also make it a potential target for the treatment of a number of intestinal, kidney and other diseases.

PBC is a rare liver disease that primarily results from autoimmune destruction of the bile ducts that transport bile acids out of the liver. The disease causes a toxic build-up of bile acids in the liver, resulting in progressive liver damage marked by chronic inflammation and fibrosis, or scarring. In response to the bile acid mediated toxicity seen in PBC, liver cells release alkaline phosphatase, or ALP, a liver enzyme that is a key biomarker of the disease pathology. Elevated blood levels of ALP are used as the primary means of diagnosis of PBC and are closely monitored in patients as the most important indicator of treatment response and prognosis.

The only approved drug for the treatment of PBC is ursodeoxycholic acid, which is available generically as ursodiol. Ursodiol is itself a bile acid that is present in small quantities in humans, and is the least detergent of the various types of bile acids that make up the bile pool. Its primary mechanism of action at therapeutic doses is to dilute more detergent bile acids, but it has no known pharmacological effects mediated by FXR or other bile acid receptors. Although ursodiol is the standard of care, studies have shown that up to 50% of PBC patients fail to respond

adequately to treatment, meaning that they continue to be at significant risk of progressing to liver failure even with treatment. The options for end-stage PBC patients who fail to respond to ursodiol are limited, and include liver transplant, which is associated with significant complications and costs. Patients typically need to take approximately one gram of ursodiol daily in divided doses, which we believe presents a compliance challenge for some patients. Given this issue, coupled with ursodiol s limited efficacy in up to 50% of PBC patients, we believe that there is a significant unmet need for a novel second line therapy in PBC. We believe that OCA has the potential to provide significant benefits in the treatment of PBC, including efficacy, pharmacological activity and ease of use.

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According to industry data, there are approximately 300,000 people with PBC in developed countries, of whom we believe approximately 60,000 have been diagnosed and are on ursodiol therapy. Based on this estimate, we believe there are up to 30,000 PBC patients who may currently be eligible for treatment with OCA. With increasing identification of PBC through routine liver function testing in primary care, we believe that there may be significantly more patients who will potentially be eligible for, and be interested in, receiving a new therapy if it becomes available on the market.

We have previously completed two randomized, placebo-controlled Phase 2 trials with OCA in PBC patients, one with OCA in combination with ursodiol and one with OCA as monotherapy. The results demonstrated that over a 12-week period single daily doses of OCA at the lowest dose of 10 milligrams (mg) met the primary endpoint in both Phase 2 trials, producing statistically significant reductions in ALP levels of greater than 20%. We consider reductions in ALP levels of greater than 10% to be a clinically meaningful improvement. Pruritus, or itching, a very common symptom in PBC patients, was the most common adverse event reported in our Phase 2 trials, with severity increasing with dose.

Our Phase 3 POISE trial has been designed to study the safety and efficacy of OCA in patients with an inadequate therapeutic response to ursodiol or who are unable to tolerate ursodiol. The primary endpoint of the 12-month double-blind portion of the POISE trial is the achievement of both an ALP level of less than 1.67 times upper limit normal, or ULN, and a minimum 15% reduction in ALP level from baseline, together with a normal level of bilirubin, a biomarker of liver function, as compared to placebo. ULN is the uppermost level of a specified parameter that is considered normal in healthy people. Patients with ALP and bilirubin levels within these thresholds have been shown in long-term studies to be at significantly lower risk of progressing to liver transplant and death.

We are advancing a once daily 10 mg dose of OCA in the POISE trial as our potential approvable dose. We recently completed an intention to treat analysis for the 10 mg dose groups in our two Phase 2 trials that was limited to those patients who would have met the POISE trial entry criteria. This analysis demonstrated that after 12 weeks of treatment approximately 40% to 45% of OCA-treated patients would have met the POISE trial primary endpoint as compared to 5% to 9% of the placebo-treated patients. In addition, 80% of OCA-treated patients across our Phase 2 trials had a reduction in ALP levels of at least 10%, as compared to 13% of placebo-treated patients.

If the POISE trial is successful, we intend to submit a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, for approval of OCA for the treatment of PBC in the United States and a Marketing Authorization Application, or MAA, to the European Medicines Agency, or EMA, for approval in Europe. Based on written scientific advice from the EMA, we believe that the EMA will accept our current clinical program as the basis for considering approval of OCA for PBC. With respect to the FDA, we intend to request that the POISE trial primary endpoint be accepted as a basis for approval of OCA under the FDA s accelerated approval regulation that enables the use of a surrogate endpoint reasonably likely to predict clinical benefit. If the FDA agrees to consider the potential approval of OCA in accordance with its accelerated approval regulation based on the POISE trial results, we will likely have to conduct a Phase 3 clinical outcomes trial to confirm the clinical benefit predicted by the biochemical therapeutic response. This Phase 3 clinical outcomes trial would have to be substantially underway at the time of the NDA submission and would be completed after accelerated approval. We are in discussions with the FDA about the details of such a clinical trial and are planning to initiate it as early as the second half of 2013.

A number of published clinical studies have demonstrated that, as a measure of therapeutic response, lower levels of ALP, on its own or in conjunction with normal bilirubin levels, correlate with a significant reduction in adverse clinical outcomes such as liver transplant and death. We believe that one of the key factors in the FDA s acceptance of our POISE trial primary endpoint as a basis for approval will be the result of additional analysis of the already available PBC clinical outcomes data. We are sponsoring an independent study involving more than ten leading PBC

centers in North America and Europe that are pooling their long-term patient data, anticipated to be from at least 4,000 patients, in order to further substantiate that our POISE trial primary endpoint is predictive of clinical benefit. We anticipate these results will be available in 2013 and will support what we believe is an emerging consensus among PBC opinion leaders concerning the clinical utility of our selected endpoint.

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In addition to PBC, we are pursuing other indications in our OCA development program, including portal hypertension, nonalcoholic steatohepatitis, or NASH, and bile acid diarrhea. The pipeline chart below shows the current stage of development of OCA for these indications, as well as the preclinical programs for our other product candidates.

* An agonist is a substance that binds to a receptor of a cell and triggers a response by that cell.

We are currently conducting an open label Phase 2a trial of OCA in patients with portal hypertension, and we anticipate receiving results from the 10 mg dose group of this trial by the end of 2012. There are currently no approved therapies for the treatment of portal hypertension, although beta blockers are commonly used to treat patients. In addition, OCA is currently being tested in a Phase 2b trial for the treatment of NASH, sponsored by the U.S. National Institute of Diabetes and Digestive and Kidney Diseases, or NIDDK, in collaboration with us. As of September 30, 2012, the NIDDK had enrolled approximately 90% of the total number of patients targeted for this trial. Based on the interim analysis that was completed in June 2012, the NIDDK decided to continue this Phase 2b trial and we anticipate that final results will be available in late 2014. There are currently no approved therapies for the treatment of NASH. In addition, investigators at the Imperial College of London initiated enrollment in July 2012 in an open label Phase 2a trial of OCA as a treatment for bile acid diarrhea.

By virtue of our patent portfolio and the proprietary knowhow of our employees and our collaborators at the University of Perugia, we believe that we hold a leading position in the bile acid chemistry therapeutic field. Through a longstanding exclusive collaboration with Professor Roberto Pellicciari, Ph.D., one of our co-founders, and certain scientists in the medicinal chemistry group at the University of Perugia, we have gained the capability to rationally design compounds that bind selectively and potently to FXR and other bile acid receptors. Starting with OCA, which was invented by Professor Pellicciari and, together with its underlying patents, was assigned to us under our agreements with him and the University of Perugia, our collaboration has resulted in a pipeline of bile acid analogs in addition to OCA, which target both FXR and a second dedicated bile acid receptor called TGR5, a target of interest for the treatment of type 2 diabetes and associated metabolic diseases. We intend to continue developing these and other product candidates as we advance our pipeline, in some cases subject to the procurement of additional funding or through strategic collaborations.

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Our Strategy

Our strategy is to develop and commercialize novel therapeutics for patients with chronic liver and other diseases, beginning with OCA for the second line treatment of PBC and other follow-on indications that we believe are underserved by existing therapies. The key elements of our strategy are to:

complete the development of OCA for its lead indication, PBC;
obtain regulatory approval of OCA for the treatment of PBC in the United States, Europe and other countries;
commercialize OCA in the United States, Europe and other countries, initially for the treatment of PBC;
continue to develop OCA in other orphan and more prevalent liver and other diseases; and
advance the earlier stage product candidates in our pipeline.

We may enter into strategic collaborations to implement our strategy.

Overview of liver function, bile acids and chronic liver diseases

The liver performs many essential functions that are crucial for survival, including the regulation of bile acid metabolism. Bile acids are natural detergent-like emulsifying agents that are released from the gallbladder into the intestine when food is ingested, and are essential for the absorption of dietary cholesterol and other nutrients. Cholesterol bound up by bile acids is taken up by the liver, where the cholesterol is then converted into one of two primary bile acids. The bile acids are then actively secreted into bile ducts, which eventually empty into the gallbladder. This digestive cycle of bile flow from gallbladder to intestine to liver and back is called the enterohepatic recirculation of bile.

In the past decade, we have learned that in addition to facilitating nutrient absorption, bile acids have a much broader role than previously realized in regulating multiple biological functions. They are also complex signaling molecules that integrate metabolic, immune and inflammatory pathways involved in the healthy functioning of various tissues and organs. For example, the actions of bile acids in the liver, intestine and kidney regulate repair mechanisms that modulate inflammation and fibrosis, or scarring, which can lead to progressive organ damage.

The biological effects of bile acids are mediated through dedicated receptors. The best understood is the farnesoid X receptor, a nuclear receptor that regulates bile acid synthesis and clearance from the liver, thereby preventing excessive bile acid build-up in the liver, which may be toxic. As a result, FXR is a target for the treatment of liver diseases such as PBC that involve impaired bile flow, a condition called cholestasis, in which the liver is exposed to higher than normal levels of bile acids, causing significant damage over time due to the detergent effects of bile acids. In addition, bile acid activation of FXR induces anti-fibrotic, anti-inflammatory and other mechanisms that are necessary for the normal regeneration of the liver. Based on the discovery of similar FXR-mediated protective mechanisms in other organs exposed to bile acids, we believe that FXR may also be a potential target for the treatment of a number of intestinal, kidney and other diseases.

Our Lead Candidate: Obeticholic Acid, or OCA, for PBC

Primary Biliary Cirrhosis

Our current clinical focus is on the development of OCA, a novel, orally administered, first-in-class FXR agonist that we believe has broad liver-protective properties and may effectively counter a variety of chronic insults to the liver that cause fibrosis, which can eventually lead to cirrhosis, liver transplant and death. Our first targeted disease is PBC,

an orphan indication with a significant unmet medical need.

PBC is a liver disease that primarily results from autoimmune destruction of the bile ducts that transport bile acids out of the liver, resulting in cholestasis. As the disease progresses, persistent toxic build-up of bile acids cause progressive liver damage marked by chronic inflammation and fibrosis.

While PBC is rare, it is the most common cholestatic liver disease. An estimated 90% of patients are women, with approximately one in 1,000 women over the age of 40 afflicted by the disease. The mean age of

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diagnosis is about 40 years and the typical initial presentation is between the ages of 30 and 65 years. In the United States, the disease is the fifth most common cause of liver transplant and accounts for approximately two percent of deaths attributed to cirrhosis. A majority of PBC patients are asymptomatic at the time of initial diagnosis, but most develop symptoms over time. Fatigue and pruritus, or itching, are by far the most common symptoms in PBC patients. Less common symptoms include dry eyes and mouth, as well as jaundice, which can be seen in more advanced disease. Based on the guidelines of the American Association for the Study of Liver Disease, or AASLD, and the European Association for the Study of the Liver, or EASL, the clinical diagnosis of PBC is established based on the presence of (i) a positive antimitochondrial antibody, or AMA, a marker of this autoimmune disease seen in up to 95% of PBC patients, and (ii) elevated serum levels of ALP, an enzyme that is released by liver cells in response to the bile acid mediated toxicity and that is a key biomarker of the disease pathology. ALP is routinely measured in blood tests and, in the earlier stages of PBC, it is often the only abnormally elevated liver enzyme, rising to between two to ten times higher than normal values. It is closely monitored in patients as an indicator of treatment response and prognosis. Bilirubin is a marker of liver function and is also monitored in PBC to provide an indication of how well the liver is functioning. Liver biopsy can be used to confirm the diagnosis of PBC, but is not required and is becoming less-frequently performed.

Disease progression in PBC varies significantly but usually is relatively slow, with median survival in untreated patients of 7.5 years if symptomatic at diagnosis and up to 16 years if asymptomatic at diagnosis. PBC patients whose disease is progressing have persistently elevated levels of ALP and other liver enzymes, with abnormal bilirubin levels heralding more advanced disease. Data from published long-term studies demonstrate that a significant portion of such patients with advancing disease progress to liver failure, transplant or death within five to ten years, despite receiving ursodiol, the standard of care therapy.

Currently Available Treatment Options for PBC

The only approved drug for the treatment of PBC is ursodiol, which is the standard initial course of therapy for all PBC patients. Ursodiol is a naturally occurring bile acid found in small quantities in humans and it is the least detergent of the various types of bile acids that make up the bile pool. In traditional Asian medicine, ursodiol obtained from bears has been used for centuries as a liver tonic for any disease or condition associated with liver malfunction. In humans, the typical daily dose of ursodiol of approximately one gram represents more than one-fifth of the entire bile pool and, after ongoing therapy, it will comprise at least half of the entire bile pool. It is believed that this results in the bile pool being less toxic to the liver due to ursodiol s dilution of other more detergent bile acids.

In patients in whom ursodiol is effective, the treatment slows the progression of PBC, reducing the likelihood of liver failure and the need for transplant. As shown in numerous clinical trials of ursodiol treatment, a positive therapeutic response is primarily determined by sustained reduction of ALP levels, along with maintenance of normal bilirubin levels, indicating adequately compensated liver function. This biochemical improvement has been shown to correlate well with improved clinical outcomes such as transplant-free survival.

Although drugs such as colchicine, budesonide, methotrexate and others have been tested as treatments in PBC, none has been shown to be both effective and safe in altering the course of the disease.

Our PBC Opportunity

While ursodiol s mechanism of action at therapeutic doses is to dilute more detergent bile acids, it has no known pharmacological effects mediated by FXR or other bile acid receptors. Although ursodiol is the established standard of care for the treatment of PBC, studies have shown that up to 50% of PBC patients fail to respond adequately to

treatment. Patients typically need to take approximately one gram of ursodiol daily in divided doses, which we believe presents a compliance challenge for some patients.

The outlook and treatment options for end-stage PBC patients who fail to respond to ursodiol are limited. Although liver transplant can be curative, many patients fail to receive a donor organ in time, and for those who do, there are very significant clinical risks, such as infection and organ rejection, as well as significant costs. In addition, the disease recurrence rate is as high as 18% at five years and up to 30% at ten years after liver transplant.

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According to industry data, there are approximately 300,000 people with PBC in developed countries, of whom we believe approximately 60,000 have been diagnosed and are on ursodiol therapy. Based on this estimate, we believe there are up to 30,000 PBC patients who may currently be eligible for treatment with OCA. With increasing identification of PBC through routine liver function testing in primary care, we believe that there may be significantly more patients who will potentially be eligible for, and be interested in, receiving a new therapy if it becomes available on the market. While ursodiol is the standard of care for the treatment of PBC, given the limitations of its efficacy and compliance with the dosing regimen discussed above, we believe that there is a significant unmet need for a novel second line therapy in PBC.

Our Solution: OCA for PBC

Overview

Our lead product candidate, OCA, is a bile acid analog and first-in-class FXR agonist derived from the primary human bile acid chenodeoxycholic acid, or CDCA. CDCA, a natural FXR agonist, has historically been used safely as a chronic therapy for cholesterol gallstone disease. We are initially developing OCA for the second line treatment of PBC for patients with an inadequate therapeutic response to ursodiol or who are unable to tolerate ursodiol. OCA has received orphan drug designation in the United States for the treatment of PBC and a related disease called primary sclerosing cholangitis, or PSC. OCA also has orphan designation in Europe for PBC. We filed an IND with the FDA for OCA for the treatment of PBC in 2006. We believe we are the first company to have advanced an FXR agonist into clinical trials and are currently enrolling our Phase 3 POISE trial to evaluate the safety and efficacy of OCA as a novel treatment in PBC. We own worldwide rights to OCA outside of Japan and China, where we have exclusively licensed the compound to DSP, which also has an option to exclusively license OCA in certain additional Asian countries.

We have completed two randomized, placebo-controlled Phase 2 trials of OCA in PBC patients. The first trial enrolled 165 patients to evaluate the addition of OCA to ursodiol in patients with an inadequate response to ursodiol therapy, and the second trial enrolled 59 patients to evaluate OCA given as monotherapy. Both trials showed that, over a 12-week period, single daily doses of OCA at the lowest dose of 10 mg met the Phase 2 primary and secondary endpoints of those trials, producing statistically significant reductions in levels of ALP and other important liver enzymes. Further, long-term open label extension phases of these trials have demonstrated that the majority of patients taking OCA for at least 12 months, with some on therapy for more than 3 years, maintained a durable treatment response.

OCA Benefits in PBC

We believe that OCA has the potential to provide the following benefits in the treatment of PBC:

Efficacy. In addition to achieving the primary endpoint in our Phase 2 trials, the data also demonstrated that 80% of OCA-treated patients across our Phase 2 trials experienced a reduction in ALP levels of at least 10%, which we consider to be a clinically meaningful improvement, as compared to 13% of placebo-treated patients. Furthermore, our analysis of the data for those Phase 2 patients who would have met the entry criteria for our POISE trial demonstrated that after 12 weeks of treatment approximately 40% to 45% of OCA-treated patients would have met the POISE trial primary endpoint, as compared to 5% to 9% of the placebo-treated patients.

Pharmacological Activity. Unlike ursodiol, which has no FXR-agonistic activity, OCA is approximately 100-times more potent than CDCA in activating the receptor. In numerous animal models, sustained FXR activation with OCA treatment has resulted in the prevention, and even reversal, of liver damage caused by progressive fibrosis. Our Phase

2 trials have demonstrated that most patients taking OCA also have significant reductions in immunoglobulin M, or IgM, and, in the combination trial with ursodiol, C-reactive protein, or CRP, common indicators of autoimmune activity. We believe that this demonstrates potential disease-modifying therapeutic activity directly addressing the underlying autoimmune pathology.

Ease of Use. We anticipate seeking approval of OCA for the treatment of PBC at a dose of a single 10 mg tablet each day, which is approximately 1/100 the amount of ursodiol that a patient is typically prescribed.

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Phase 3 PBC Program for OCA

We are currently enrolling our Phase 3 POISE trial, which has been designed to study the safety and efficacy of OCA in PBC patients with an inadequate therapeutic response to ursodiol or who are unable to tolerate ursodiol. In this trial, eligible PBC patients currently taking a stable therapeutic dose of ursodiol will continue their ursodiol treatment and be randomized into one of three trial arms of 60 patients each, adding either: 10 mg of OCA; 5 mg of OCA increasing over the course of the trial to 10 mg of OCA; or a placebo. The double-blind phase of the trial is designed to be 12 months in duration, and patients completing this phase will continue in an open label, long-term safety extension phase for another five years, during which all patients will receive OCA treatment with doses as low as 5 mg and as high as 25 mg a day, as clinically indicated.

The primary endpoint of the 12 month double-blind portion of the POISE trial is the achievement of both a reduction in ALP level to below a threshold of 1.67 times upper limit normal, or ULN, with a minimum of 15% reduction in ALP level from baseline, and a normal bilirubin level, compared to placebo after 12 months of therapy. In order to be eligible to enter the POISE trial, patients must have previously met the diagnostic criteria for PBC and have been taking a therapeutic dose of ursodiol for at least 12 months or, if unable to tolerate ursodiol, patients must not have been on therapy for at least three months prior to entering the trial. In addition, patients must have ALP levels of at least 1.67 times ULN and/or bilirubin levels of one to two times ULN. The POISE trial is designed to enroll 180 patients across approximately 60 clinical sites in North America and Europe. As of September 30, 2012, we had enrolled approximately two-thirds of the total number of patients targeted for our POISE trial, and we currently expect results from the trial to be available by mid-2014.

The chart below shows an analysis of the extracted intention to treat data for the 10 mg dose groups in our two Phase 2 trials based on patients who would have met the inclusion criteria for entry in the POISE trial. The analysis demonstrated that after 12 weeks of treatment, approximately 40% to 45% of OCA-treated patients in our Phase 2 trials would have met the POISE trial primary endpoint.

If the POISE trial is successful, we intend to submit a NDA to the FDA for approval of OCA for the treatment of PBC in the United States and a MAA to the EMA for approval in Europe. Based on written scientific advice from the EMA, we believe that the EMA will accept our current clinical program as the basis for considering approval of OCA for PBC. With respect to the FDA, we intend to request that the POISE trial primary endpoint be accepted as a basis for approval of OCA under the FDA s accelerated approval regulation

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that enables the use of a surrogate endpoint reasonably likely to predict clinical benefit. If the FDA agrees to consider the potential approval of OCA in accordance with its accelerated approval regulation based on the POISE trial results, we will likely have to conduct a Phase 3 clinical outcomes trial to confirm the clinical benefit predicted by the biochemical therapeutic response. This Phase 3 clinical outcomes trial would have to be substantially underway at the time of the NDA submission and would be completed after accelerated approval. We are in discussions with the FDA about the details of such a clinical trial and are planning to initiate it as early as the second half of 2013.

A number of published clinical studies have demonstrated that a reduction in ALP or attaining an ALP below specific thresholds correlates with significant reduction in adverse clinical outcomes, such as liver failure, transplant and death. Similarly, studies have demonstrated that elevated bilirubin levels are predictive of adverse outcomes. We believe that one of the key factors in the FDA s acceptance of our POISE trial primary endpoint as a basis for approval will be the result of additional analysis of the already available PBC clinical outcomes data. We are sponsoring an independent study involving more than ten leading academic PBC centers in Europe and North America that are pooling their long-term patient data to further substantiate that the POISE trial primary endpoint is predictive of clinical benefit. We anticipate these results will be available in the second quarter of 2013 and will support what we believe is an emerging consensus among PBC opinion leaders concerning the clinical utility of our selected endpoint. We are calling this collection of centers the PBC Supergroup and it is anticipated that data from at least 4,000 patients will be submitted.

We believe this study will comprise the single largest analysis of outcomes in PBC patients and that the analysis will confirm the results already published, or made available to us, by four different members of the PBC Supergroup (University of Toronto, Mayo Clinic, University of Paris and Erasmus University (Rotterdam)). These groups have independently corroborated that the achievement of an ALP level of less than 1.67 times ULN, together with a normal bilirubin level, correlate with a significant reduction of risk of adverse clinical outcomes such as liver transplant and death.

Summary of additional preclinical and clinical studies required for regulatory submissions

Based on our interactions with the FDA and EMA, we believe that, in addition to the successful completion of the POISE trial, we will need to complete the following clinical studies prior to our planned NDA and MAA filings:

long-term monotherapy safety extension studies, resulting in approximately 650 patient cumulative years of safety data across all clinical trials;
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 clinical pharmacology trials, including, but not limited to, drug interactions, the effects of food and drug-disease interaction studies.

In addition, other preclinical studies that we will need to complete are carcinogenicity studies in two rodent species, which were initiated in early 2012, and reproductive toxicology studies. Finally, before we submit a NDA to the FDA, we believe that we will need to be substantially underway with a Phase 3 clinical outcomes trial to confirm clinical benefit at the time of NDA submission. We are in discussions with the FDA about the details of such a clinical trial and are planning to initiate it as early as the second half of 2013. It is possible that the FDA may require that we conduct and/or complete additional clinical trials and preclinical studies before it will consider our NDA for approval.

Summary of Completed OCA PBC Clinical Trials

Phase 2 Trial: OCA as Combination Therapy in PBC Patients

We have completed a double-blind, placebo-controlled Phase 2 clinical trial of OCA in 165 patients with PBC. The trial evaluated the effects of adding one of three doses of OCA (10 mg, 25 mg and 50 mg) or placebo to ursodiol therapy in patients with ALP levels of higher than 1.5 times ULN who had not responded adequately to ursodiol therapy alone. Patients continued their prior ursodiol dose throughout the trial. The trial was comprised of a 12-week treatment period, with a two-week follow up. At the end of the 12-week treatment period, all three doses of OCA added to ursodiol therapy produced statistically significant reductions

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in ALP levels as compared with patients receiving placebo plus ursodiol therapy, the primary endpoint. OCA-treated patients demonstrated a mean reduction of 21% to 25% in ALP levels, as compared to patients receiving placebo plus ursodiol therapy, who exhibited a mean reduction of less than 3%. At trial entry, the baseline mean ALP value for all the patient groups was approximately 2.4 times ULN. In addition, patients who received OCA experienced similar significant decreases in other clinically relevant liver enzymes such as gamma glutamyl transferase, or GGT, aspartate transaminase, or AST, alanine transaminase, or ALT, and bilirubin. Furthermore, serum markers of inflammation and immune response also improved as seen in reductions of CRP and IgM, which are closely associated with autoimmune dysfunction in PBC.

With the exception of a higher incidence of pruritus in the two highest OCA dose groups and a higher incidence of severe pruritus in all OCA dose groups, the Phase 2 clinical trial data showed that adverse events were generally similar across all groups, including the placebo group. Pruritus was dose dependent, with the ursodiol plus placebo incidence at 50%, ursodiol plus 10 mg of OCA at 47%, ursodiol plus 25 mg of OCA at 85% and ursodiol plus 50 mg of OCA at 80%. However, the severity of pruritus and the discontinuation rate due to severe pruritus increased with OCA dose and was worse than seen with placebo. There were no other statistically significant side effects observed over the placebo group, except for mild nausea.

Open Label Long-Term Safety and Efficacy Trial for OCA as Combination Therapy

Following the completion of the double-blind portion of the Phase 2 combination trial described above, 78 patients were enrolled in an open label long-term safety and efficacy extension study, or LTSE. Of these patients, 19 subsequently discontinued their participation in the LTSE, ten due to pruritus, one due to elevated bilirubin and eight due to other adverse events or for other reasons. There were five serious adverse events in the LTSE, of which two occurred at each of the 10 mg and 25 mg doses and one occurred at the 50 mg dose. None of the serious adverse events, which were typically related to hospitalizations for pre-existing conditions, was considered likely to be related to OCA therapy, and no serious adverse event was considered to be hepatic in nature.

In the LTSE, patients continued to receive open label OCA, increasing from a dose of 10 mg to as high as 50 mg each day. In patients whose dose was increased, there was a benefit of increasing the dose up to 25 mg from 10 mg (with an incremental 9% fall in ALP), but not in increasing the dose above 25 mg. Over two-thirds of the patients were increased to 20 mg or more. Pruritus was the most common adverse event, reported in 68 of the 78 patients (approximately 87%). Other adverse events included fatigue, insomnia and upper respiratory tract infection, each of which was reported by approximately 13% of the patients in the LTSE.

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The chart below demonstrates that patients taking OCA achieved mean reductions in ALP to approximately 1.67 times ULN after having been on therapy for three months and maintained that treatment response throughout a 12-month period and beyond. Furthermore, after 12 months, more than 50% of the patients had met the Phase 3 POISE trial primary endpoint, with a reduction in ALP levels to below 1.67 times ULN, along with at least a 15% reduction in ALP, and a normal bilirubin level. Taken together with the data from our ongoing monotherapy LTSE trial discussed below, we believe that these LTSE phases of our Phase 2 trials demonstrate that a large majority of patients taking OCA for at least 12 months, with some currently on therapy for more than 3 years, maintain a durable therapeutic response.

Phase 2 Combination Trial LTSE

* SEM is defined as the standard error of the mean, which is a statistical estimate of the amount that an obtained mean may be expected to differ by chance from the true mean.

Phase 2 Trial: OCA as Monotherapy in PBC Patients

We have completed a 59 patient double-blind, placebo-controlled Phase 2 clinical trial of OCA given as a monotherapy to patients with PBC. The trial evaluated the effects of 10 mg and 50 mg doses of OCA compared to placebo in patients with baseline ALP levels of higher than 1.5 times ULN. Patients either had never taken ursodiol or had not been taking ursodiol for at least 3 months before the start of the trial. The trial was comprised of a 12-week treatment period, with a two-week follow up. At the end of the 12-week treatment period, statistically significant reductions in ALP were seen in the treated patients (38% to 45% mean ALP reductions compared with no change in the placebo-treated patients). Patients in the 10 mg dose group experienced absolute reductions in ALP levels from a mean of approximately 3.9 times ULN to approximately 1.9 times ULN at the end of the study. Even greater reductions in GGT (63% to 75%) were seen in the OCA-treated groups (compared to 3% for placebo-treated groups). There were also significant improvements in ALT levels and bilirubin levels. In addition, IgM also improved. Pruritus was seen more commonly in the patients treated with OCA, with the incidence, severity and discontinuation rate all increasing with dose; otherwise, the other adverse events were not clearly different across the groups.

Ongoing Open Label Long-Term Safety and Efficacy Trial for OCA as a Monotherapy

Following the completion of the double-blind portion of the Phase 2 monotherapy trial described above, some patients were given the option to enroll in an open label long-term safety and efficacy extension study, or monotherapy LTSE. The monotherapy LTSE phase is currently ongoing. Patients continue to receive open label OCA in this phase, and have been increased from a starting dose of 10 mg to as high as 50 mg.

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Approximately half of the patients are currently taking 20 mg or more of OCA. Consistent with the combination trial LTSE, continued improvements in biochemistry have been seen. Pruritus is the most common adverse event and has been reported over the course of the monotherapy LTSE in 24 of the 28 subjects (or 86%) for whom data are available. Other adverse events include headache, arthralgia, fatigue and nausea, which have been reported in approximately 32%, 25%, 21% and 21% of the patients, respectively.

Summary of Completed Phase 1 Trials

OCA has been evaluated in two Phase 1 clinical trials to study its safety and pharmacokinetic profile in healthy volunteers. The first was a single ascending dose trial in 24 subjects testing single OCA doses in the range of 50 mg to 500 mg. The second was a multiple ascending dose trial in 50 subjects testing repeated OCA doses in the range of 25 mg to 250 mg for 12 consecutive days. Adverse events seen in the Phase 1 trials were generally mild. Only two adverse events, upper abdominal pain and nasopharyngitis, were observed in one subject each in the single ascending dose trial. In the multiple ascending dose trial, doses from 25 mg to 100 mg were generally well-tolerated. At the highest dose of 250 mg, ALT and AST increases were seen, consistent with our animal toxicology data. This dose is 25-times greater than the 10 mg dose in the POISE trial and ten-times greater than the 25 mg dose being tested in our ongoing Phase 2b trial for NASH, called the FLINT trial. Half of the subjects in the 250 mg dosing group reported mild pruritus and one discontinued due to a rash.

Additional Potential Clinical Indications for OCA

Based on the potential protective effects of OCA in the liver, we are conducting clinical trials in additional chronic liver disease indications with potential greater market opportunities, with the view of expanding OCA s therapeutic applications.

Potential Use of OCA to Treat Portal Hypertension

A study in an animal model of cirrhosis showed that OCA treatment can acutely reverse portal hypertension through a localized vasodilatory mechanism that is independent of its longer term anti-fibrotic effects. Portal hypertension results from increased pressure in the portal vein, which feeds most of the blood supply to the liver. The condition typically occurs as the liver becomes cirrhotic and more rigid, thereby offering more resistance to blood inflow from the portal vein. Many patients with liver cirrhosis go on to develop portal hypertension, which is a common cause of morbidity and mortality at the end stage of all chronic liver diseases. An early manifestation of portal hypertension is the development of esophageal varices, which are distended and weakened veins in the lower part of the esophagus that can burst and cause catastrophic bleeding. There are no approved therapies for the treatment of portal hypertension, although beta blockers are commonly used to treat patients. However, they are effective in only 25% to 33% of patients and have significant safety issues in portal hypertension patients. It has been shown clinically that reducing pressure in the portal vein can lower the risk of adverse outcomes such as the incidence of variceal bleeding. We believe that portal pressure reduction is an appropriate therapeutic endpoint to demonstrate clinical proof-of-concept.

Phase 2 Trial for Portal Hypertension

OCA is currently being tested in an open label Phase 2a trial, called the PESTO trial, in patients with portal hypertension to evaluate the ability of OCA to reduce hepatic portal venous pressure in patients with end-stage liver disease. The primary endpoint of the trial is to lower the hepatic venous pressure gradient after seven days of treatment by 15% or more, or to 12 mm Hg or less, a level at which the risk of adverse clinical outcomes has been

shown to be significantly reduced. An initial safety cohort of four patients demonstrated that OCA was well-tolerated at the 10 mg dose. We are currently conducting an efficacy trial of the 10 mg dose in seven to nine patients, while also completing a safety cohort at a 25 mg dose before continuing with a planned efficacy cohort at this higher dose. We anticipate receiving results from the 10 mg dose group of our PESTO trial by the end of 2012. We are utilizing the data from this trial to supplement our safety data set for our planned NDA for PBC to include the evaluation of OCA in patients with end-stage liver disease. If the PESTO trial supports the further development of OCA for the treatment of portal hypertension, we may initiate a Phase 2 clinical trial in patients with portal hypertension. However, we will need to secure funding in addition to the proceeds from this offering to continue to advance OCA for this indication.

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Potential Use of OCA to Treat Nonalcoholic Steatohepatitis (NASH)

FXR activation has been shown to play a key role in the regulation of the metabolic pathways relevant to NASH, highlighting FXR as a potential drug target for treatment of the disease. Nonalcoholic fatty liver disease, or NAFLD, is believed to be the most common chronic liver disease worldwide and we believe that more than 75 million patients are affected in the United States alone. The disease is associated with the Western diet, which is rich in processed foods with high fat and sugar content. NAFLD can lead to excessive fat accumulation in the liver, insulin resistance and increased risk of developing metabolic syndrome, type 2 diabetes and cardiovascular disease. A subset of approximately 30% of NAFLD patients develop NASH, which is a more serious liver disease. In these patients, for reasons that are still not completely understood, the fat build-up in the liver induces chronic inflammation which leads to progressive fibrosis that can lead to cirrhosis and liver failure.

NASH is currently diagnosed by liver biopsy. Studies have shown that at least 15% of NASH patients will develop liver cirrhosis over a ten to 15 year period. In the United States, the most recent epidemiological studies have concluded that more than 12% of the general population has NASH, while approximately 2.7%, or more than eight million patients, have advanced liver fibrosis or cirrhosis due to the disease. In the past decade, the proportion of liver transplants attributed to NASH increased from 1% to 10%, establishing NASH as the third leading and a rapidly increasing indication for liver transplant in the United States. The epidemiological data from other developed countries in Europe and Japan are similar, and NASH has also become a highly prevalent liver disease in developing countries such as India and China.

There are currently no drugs approved for the treatment of NAFLD or NASH. It has been reported that in 2010, there were approximately $615 million in off-label sales of various therapeutics for the treatment of NASH, such as insulin sensitizers (e.g., metformin), antihyperlipidemic agents (e.g., gemfibrozil), pentoxifylline and ursodiol. Lifestyle changes and exercise to reduce body weight and treatment of concomitant diabetes and dyslipidemia are accepted as the standard of care but have not conclusively been shown to prevent disease progression.

Ongoing Phase 2 Trial for NASH

OCA is currently being tested in a Phase 2b NASH trial, called the FLINT trial, that is testing a 25 mg single daily dose of OCA versus placebo in 280 patients with NASH. We are sponsoring the FLINT trial in collaboration with the U.S. National Institute of Diabetes and Digestive and Kidney Diseases, or NIDDK, which oversees a clinical research network of eight leading NASH centers in the United States. The NIDDK filed an IND with the FDA for OCA for the treatment of NASH in 2010. The primary endpoint in the 72-week double-blind FLINT trial is based on liver biopsy and is defined as an improvement of two or more points in the NAFLD activity score (a system of scoring the histopathological features in the liver) with no worsening of liver fibrosis. The NIDDK is providing the majority of funding for the trial. As of September 30, 2012, the NIDDK had enrolled approximately 90% of the total number of patients targeted for the FLINT trial, and we anticipate the trial will be fully enrolled in 2012, with final results expected in late 2014. If this trial supports the further development of OCA as a treatment for NASH, we anticipate that we will need to secure additional funding to advance OCA for this indication.

In June 2012, the NIDDK s data and safety monitoring board, or DSMB, for the FLINT trial completed an interim analysis and recommended that the trial should continue based on data from 101 patients who had completed at least 24 weeks and up to 15 months of the trial. The interim analysis reviewed the change from baseline in ALT levels as the efficacy criterion variable and all available safety data. Based on the recommendation of the DSMB, the NIDDK decided to continue the FLINT trial.

Phase 2 Trial: OCA as Therapy in Type 2 Diabetic Patients with NAFLD

We have also completed a Phase 2 clinical trial of OCA in 64 type 2 diabetic patients with NAFLD. This double-blind, placebo-controlled trial tested 25 mg and 50 mg doses of OCA over a six-week period and assessed the effects of OCA on insulin sensitivity. The trial demonstrated that OCA therapy significantly improved insulin sensitivity both in the liver and peripheral tissues, thereby meeting the primary endpoint in the trial. Significant improvements in weight loss and reductions in liver enzymes such as GGT and ALT were also noted. The trial also showed that OCA was well-tolerated by the trial patients, with side effects no different than those reported on placebo (apart from mild constipation in the 50 mg group).

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Potential Use of OCA to Treat Bile Acid Diarrhea

In July 2012, investigators at the Imperial College of London initiated enrollment of an open label Phase 2a trial, called the OBADIAH trial, to investigate whether OCA can stimulate the hormone known as fibroblast growth factor 19, or FGF19, in patients with bile acid diarrhea. Bile acid diarrhea is an under-recognized but common subtype of inflammatory bowel syndrome with diarrhea, or IBS-D, marked by chronic watery diarrhea. FGF19 levels are substantially reduced in these patients, resulting in impaired feedback inhibition of bile acid synthesis. The resulting excess bile acids spill into the intestine where they produce diarrhea by stimulating intestinal secretion. FGF19 is synthesized in the small intestine under the direct regulation of FXR and we have shown in all three of our completed Phase 2 trials that OCA markedly stimulates the release of FGF19. The primary outcome measure of the OBADIAH trial will be to assess the change in FGF19 levels over a two-week period in ten patients with bile acid diarrhea and in two control groups. The Imperial College of London is acting as the sponsor of the OBADIAH trial. If positive, this trial could support the further development of OCA for the treatment of bile acid diarrhea, in which case we would need to secure additional funding for the advancement of OCA for this indication. We currently anticipate that the enrollment for the OBADIAH trial will be completed in the first quarter of 2013 and that results will be available in mid-2013.

Other Potential Indications for OCA

We believe that OCA may have potential therapeutic application in other chronic diseases such as PSC, another autoimmune cholestatic liver disease; inflammatory bowel disease, including Crohn s disease and/or ulcerative colitis; biliary atresia, a pediatric disease characterized by deficient bile duct development; and Aligille Syndrome, a very rare genetic disorder that affects the liver and other organs. We anticipate that we will need to secure additional funding for the advancement of OCA for any of these indications.

Potential Future Product Candidates

In addition to OCA, we have other novel bile acid analog compounds targeting FXR and a second dedicated bile acid receptor called TGR5, which is a target of interest for the treatment of type 2 diabetes. We intend to continue advancing these and other product candidates as we build our pipeline, in some cases subject to the procurement of additional funding.

INT-767

INT-767 is an orally administered dual FXR and TGR5 agonist that, like OCA, is derived from the primary human bile acid CDCA. This product candidate has been shown to be approximately five-times more potent than OCA as an FXR agonist. In animal models of chronic liver, intestinal and kidney diseases, INT-767 has consistently demonstrated greater anti-fibrotic and anti-inflammatory effects than OCA. We own exclusive worldwide, royalty-free rights to INT-767.

We currently plan to advance INT-767 through the preclinical studies required to support the advancement of this product candidate to an IND, with an intended focus on developing it as a novel treatment for chronic kidney diseases, such as diabetic nephropathy, that involve progressive fibrosis leading to kidney failure. If the preclinical and Phase 1 clinical data support the advancement of INT-767 into Phase 2 clinical trials, we anticipate that we will need to secure additional funding for the further development of this compound.

INT-777

INT-777 is an orally administered TGR5 agonist that is derived from the primary human bile acid cholic acid. We have completed the preclinical studies necessary for the filing of an IND. We own exclusive worldwide, royalty-free rights to INT-777. In order to advance this product candidate into clinical trials, we will need to secure additional funding and may seek a strategic collaborator.

Our in vitro studies of INT-777 showed that the product candidate has the potential to selectively target TGR5, a receptor that has been shown to directly regulate the release of glucagon like peptide-1, or GLP-1, in the intestine with resulting insulin sensitizing effects. There are several important and effective marketed drugs that enhance the effects of GLP-1 through different mechanisms, but none are able to induce the endogenous production of this hormone, and we believe there is interest in the potential for a TGR5 agonist to provide additive benefits. TGR5 has also been shown in animal models to regulate other metabolic pathways in brown fat and skeletal muscle that drive energy expenditure. The receptor may also play a role in the control of inflammation, which is increased in insulin resistant diabetic conditions.

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In animal models of diabetes, treatment with INT-777 induced GLP-1 secretion, with resulting insulin sensitivity and normalization of glycemic control, increased basal energy expenditure and prevention of weight gain, and a reduction in blood lipid levels together with liver steatosis and fibrosis. We believe that these preclinical results could support further development of INT-777 and our other TGR5 agonists in the treatment of type 2 diabetes and associated metabolic disorders.

Strategic Collaborations and Research Arrangements

Dainippon Sumitomo Pharma

On March 29, 2011, we entered into a license agreement with Dainippon Sumitomo Pharma Co. Ltd., or DSP, under which we granted DSP an exclusive license to research, develop and commercialize OCA as a therapeutic for the treatment of PBC and NASH in Japan and China (excluding Taiwan). Under the terms of the agreement, DSP is required to use commercially reasonable efforts to develop and commercialize OCA in Japan and China for the treatment of PBC and NASH, and we are obligated under the agreement to use commercially reasonable efforts to develop OCA outside of Japan and China. DSP has agreed during the term of the agreement to not commercialize any compound that is a FXR agonist for use in the treatment of PBC or NASH other than pursuant to the agreement.

We granted DSP an option under the agreement to obtain an exclusive license to commercialize OCA for indications other than PBC and NASH on the same terms as are set forth in the agreement. DSP may exercise this option with respect to any indication at any time during the two-year period commencing on the date we notify DSP of the commencement of a Phase 3 clinical trial involving OCA for such indication, subject to DSP s payment of an option fee for each additional indication. No option fee is required to be paid by DSP if it exercises its option for any additional indication only in China.

We also granted DSP an option under the agreement to add Korea, Taiwan, Malaysia, Vietnam, the Philippines, Thailand, Singapore and/or Indonesia to its exclusive license on the same terms as are set forth in the agreement. DSP may exercise this option with respect to any such country at any time up until the date on which regulatory approval to commercialize OCA is granted in Japan, subject to DSP s payment of an option fee for each country. We may not offer rights to a third party to develop and commercialize OCA in any of these countries for an agreed upon time period, and, if after this date, we accept or make a bona fide offer of exclusive rights to a third party to develop and commercialize OCA in any of these countries, we must first notify DSP and DSP has the right to exercise its option with respect to any such country. In addition, prior to accepting or making a bona fide offer of any exclusive development and commercialization rights involving OCA in the United States and Canada to a third party, we must first engage in good faith negotiations with DSP with respect to the grant to DSP of exclusive rights to develop and commercialize OCA in such countries.

DSP made an up-front payment to us in the amount of $15.0 million upon execution of the agreement. In addition, DSP may be required to pay us up to an aggregate of approximately $30.0 million for the achievement of development milestones, $70.0 million for the achievement of regulatory approval milestones and $200.0 million for the achievement of sales milestones based on aggregate sales amounts. DSP is also obligated to pay us tiered royalties ranging from the tens to the twenties in percent based on net sales of OCA products in Japan and the other Asian countries covered by this agreement. The term of the agreement, and DSP s obligation to pay royalties to us for each OCA product, expires on a country-by-country basis on the later of the expiration of the exclusivity period in such country, whether through the expiration of applicable patents or the introduction of generic drugs that compete with the OCA product, or ten years after the first commercial sale of such OCA product for the first or second indication in that country. Royalty rates are subject to reduction under the agreement in specified circumstances, including, with

respect to any country in the exclusive territory, if sales of generic products reach a certain threshold market share in that country over a specified period.

DSP may terminate the agreement in its entirety or on a country-by-country or indication by indication basis upon 90 days written notice. Either we or DSP may terminate the agreement in the event of the uncured material breach by or bankruptcy of the other party, subject to certain dispute resolution procedures. If DSP were to terminate the agreement for our material breach, it would have a perpetual license following the effective date of termination, subject to the payment by DSP of a royalty based on net sales of OCA products, the amount of which will depend on whether the effective date of termination occurs prior to or after the date

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of first commercial sale of an OCA product. If we were to terminate the agreement for DSP s material breach or if DSP were to voluntarily terminate the agreement, DSP s license under the agreement would terminate.

Les Laboratories Servier and Institut de Recherches Servier

On August 1, 2011, we entered into a research, development, license and commercialization agreement with Les Laboratories Servier and Institut De Recherches Servier under which we 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, and Servier granted us an exclusive royalty-free license to research and develop such compounds for use in the treatment of diabetes, obesity, atherosclerosis and reperfusion injury in the United States and Japan. Under the terms of the agreement, Servier is required to use commercially reasonable efforts to develop compounds outside the United States and Japan and we are required to use commercially reasonable efforts to develop compounds in the United States and Japan.

We are obligated to conduct and are conducting a research program under the agreement to identify and optimize compounds that meet certain specified criteria sufficient for further development by Servier. The initial term of the research program is one year, subject to extension by mutual agreement. We are obligated under the agreement to provide Servier with a specified number of full time equivalent employees for the research program up to a specified maximum per year. In July 2012, the term of the research program was extended until January 31, 2013 on the same financial terms as the original research program, including the reimbursement by Servier of the full time equivalent costs incurred by us in the conduct of the research program, up to a set maximum amount.

Servier has agreed to pay for the development costs we or Servier incur in conducting certain preclinical trials and clinical trials with respect to any compound that meets specified criteria. We have 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 we enter into a partnership agreement, or commence development or commercialization activities on our own, with respect to a compound in the United States. Servier may credit a portion of any such reimbursable development costs against any milestone or royalty payments due and payable by Servier under the agreement until all such reimbursable amounts are repaid. We have not incurred any such development costs since inception, and we do not anticipate incurring any such development costs during fiscal 2012. In addition, if we enter into a partnership agreement with respect to a compound developed under the agreement solely in Japan, we and Servier have agreed to enter into good faith negotiations regarding the terms and conditions applicable to the reimbursement of development costs. If we do not enter into a partnership agreement with respect to the compound in the United States or Japan within three years from the date regulatory approval is received for a compound in the European Union, Servier will have the first right to negotiate with us regarding the terms and conditions applicable to the grant to Servier of an exclusive license to develop and commercialize the product in the United States and/or Japan.

We have the right to conduct clinical trials and obtain regulatory approvals involving compounds developed under the agreement at our sole expense in the United States and Japan, and Servier has the right to conduct clinical trials and obtain regulatory approvals involving compounds developed under the agreement at its sole expense in all other countries. We and Servier have agreed during the term of the research program not to research or develop any TGR5 agonist and, during the term of the agreement, not to commercialize any TGR5 agonist covered by the agreement other than pursuant to the agreement. However, this provision does not restrict us from developing INT-767 and INT-777.

Servier has made an up-front payment to us in the amount of €1.0 million upon execution of the agreement and has agreed to reimburse us for a portion of the full time equivalent costs incurred by us in the conduct of the research program, up to a set maximum amount. In addition, Servier may be required to pay us up to an aggregate of approximately €8.5 million for the achievement of development milestones, €10.0 million for the achievement of regulatory submission and approval milestones and €90.0 million for the achievement of sales milestones based on aggregate sales amounts. Servier is also obligated to pay us tiered single digit percentage royalties based on net sales of products developed under the agreement on a country-by-country basis. Servier s obligation to pay royalties for each product expires on a country-by-country basis

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upon the later of the expiration of the last to expire patent licensed by us that covers the product and ten years from the date of first commercial sale of that product. Royalty rates are subject to reduction under the agreement in specified circumstances, including with respect to any country if sales of generic products reach a certain threshold in that country.

The agreement expires when no payment obligations are or will become due. Servier may terminate the agreement at any time for any reason or if we consummate a change of control transaction. Either we or Servier may terminate the agreement in the event of the uncured material breach or insolvency of the other party. Upon the termination of the agreement by Servier for our material breach or insolvency, Servier may, at its election, have its license from us under the agreement become perpetual and royalty-free following the effective date of termination. Upon termination of the agreement by Servier without cause, we will maintain our rights to the technology licensed to Servier outside of the United States and Japan and Servier will pay us the balance of any unpaid funding under the research program. Upon the termination of the agreement by us for Servier s material breach or insolvency, we may, at our election, have our license from Servier under the agreement become perpetual following the effective date of termination.

National Institute of Diabetes and Digestive and Kidney Diseases

In July 2010, we entered into a cooperative research and development agreement, or CRADA, with the National Institute of Diabetes and Digestive and Kidney Diseases, or NIDDK, a division within the National Institutes of Health, to conduct our ongoing Phase 2b FLINT trial for the treatment of NASH with OCA. In June 2012, the DSMB for the FLINT trial completed an interim analysis and recommended that the trial should continue based on data from 101 patients who had completed at least 24 weeks and up to 15 months of the trial. The interim analysis reviewed the change from baseline in ALT levels as the efficacy criterion variable and all available safety data. The primary endpoint of the FLINT trial is based on liver biopsy. Based on the recommendation of the DSMB, the NIDDK steering committee decided to continue the FLINT trial.

The NIDDK is providing the majority of funding for the trial. In accordance with the terms of the CRADA, we have made payments of $1,750,000 to date, including a milestone payment of $1.0 million in June 2012. We will be required to make an additional $1.25 million payment within 60 days of full enrollment of the FLINT trial, which is expected to occur in 2012.

Under the terms of the CRADA, any inventions under the CRADA will be owned by the party that produced such inventions. However, any inventions jointly developed by the parties will be jointly owned. We will have the first opportunity to file patent applications in respect of any jointly developed inventions under the CRADA. If we do not exercise our rights, the NIDDK will be able to file a patent application in respect of such inventions.

The CRADA provides that we have an exclusive option to an exclusive or nonexclusive commercialization license on any inventions made solely by the NIDDK under the CRADA. The U.S. government has also been granted a worldwide, nonexclusive, nontransferable, irrevocable, paid-up license in respect of any subject inventions under the CRADA, including inventions made solely by us to the extent that such license is for research or other government purposes.

The CRADA has a term of four years, ending in July 2014. The parties to the CRADA may terminate the CRADA by mutual written consent. Either party may terminate the CRADA at any time by providing 60 days prior written notice to the other party. However, if we unilaterally terminate the CRADA, the NIDDK may be entitled to retain any funds transferred to the NIDDK under the CRADA and, unless the termination was for safety reasons, we may be required to supply sufficient quantities of OCA and placebos to complete the trial. We have agreed that the NIDDK may

continue developing OCA if we suspend the development of OCA without transferring our development efforts, assets and obligations to a third party within 90 days of discontinuation. In such circumstances, we would also be required to grant a nonexclusive, irrevocable worldwide, paid up license for any of our inventions relating to OCA, its manufacture and any method of use of OCA for the treatment of NASH, including the right to sublicense.

If the FLINT trial supports the further development of OCA for NASH, we anticipate that we will need to secure additional funding for the further development of OCA in NASH.

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University of Perugia and Professor Roberto Pellicciari

On January 1, 2012, we entered into a sponsored research agreement with the University of Perugia and Professor Roberto Pellicciari, whom we refer to as the Research Parties, to research and realize improvements to the process for synthesizing and supplying gram scale reference standard quantities of OCA, INT-767 and INT-777. Professor Pellicciari is one of our founders.

Pursuant to this agreement, we are obligated to pay the University of Perugia an aggregate of €80,000 during the term of the agreement in quarterly installments of €20,000.

Under the terms of the sponsored research agreement, we have been assigned all rights, title and interest in patent rights and technology upon creation related to the research project, effective as of the date of creation. We have the right and final decision-making ability as to the filing, prosecution or maintenance of all patents or patent applications covering any patent rights or technology developed through the agreement. The Research Parties are required to promptly and fully disclose to us in writing any invention conceived and/or reduced to practice in the conduct of the agreement. Under the terms of the agreement, we have a right of first refusal to negotiate terms to expand the agreement prior to the end of its term, or upon renewal, to include certain other research programs.

The sponsored research agreement has a term of one year from the date of execution and the agreement provides that the parties will commence discussions on renewal no later than 60 days prior to the end of the term. Either we or the Research Parties may terminate the agreement in the event of the uncured material breach of the other party after receipt of notice in writing of such breach from the other party. If the agreement is terminated by the Research Parties for a material breach by us during any quarterly period, the agreement provides that the Research Parties will be entitled to all rights, title and interest in and to the patent rights and technology created and assigned to us during that quarterly period. If the agreement is terminated by us for a material breach by the Research Parties, the agreement provides that all funds paid by us to the Research Parties not expended or irrevocably committed upon the effective date of termination will be refunded to us. Also, Professor Pellicciari will be required to return all materials and tangible documentation containing confidential information. We may also terminate the agreement if Professor Pellicciari is unable or unwilling to continue to conduct research or otherwise perform his obligations under the agreement.

TES Pharma Srl

On August 1, 2011, we entered into a research and development agreement with TES Pharma Srl, or TES, to conduct research and development activities for our TGR5 program. The research program is managed by Professor Roberto Pellicciari, who is an owner of TES.

We are required under the agreement to pay TES an aggregate amount of €250,000 each quarter during the term of the agreement. Payments will be made on a quarterly basis. The agreement provides that any funds paid to TES that have not been expended or irrevocably committed will be refunded to us.

Under the terms of the agreement, any inventions created in connection with the activities performed under the agreement will be our sole and exclusive property and all original works of authorship made by TES within the scope of the project that are protectable by copyright are works made for hire. TES has agreed to assign to us all of its rights, titles and interests in all inventions and other intellectual property rights under the agreement.

The agreement has a term of one year unless we, in our sole discretion, extend 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 our research program with Servier on the same financial terms as our original agreement with TES. Either we or TES may terminate the agreement in the event of an uncured material breach after receipt of written notice in of such breach from the other party. If we terminate the agreement for a material breach by TES, any funds paid to TES that have not been expended or irrevocably committed by them will be returned to us. TES is also obligated to deliver to us all remaining compounds and tangible documentation containing confidential information upon our request. If the agreement is terminated by TES for a material breach by us, TES is entitled to the balance of payments owed to them once the appropriate quarterly reports have been submitted to us.

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Consulting Agreements with Professor Pellicciari

Servier TGR5 Agonists

On August 1, 2011, we entered into a consulting agreement with Professor Roberto Pellicciari to provide scientific guidance for a research program relating to selective or non-selective TGR5 agonists to be undertaken by TES and to supervise and coordinate this research program. Professor Pellicciari will also act as our designated representative on a joint steering committee formed pursuant to our collaboration agreement with Servier.

The agreement provides that Professor Pellicciari will receive compensation at an annual rate of €150,000 for his services during the term of the agreement in quarterly installments of €37,500. The agreement also provides that Professor Pellicciari will be eligible for a €50,000 performance bonus based on the success of the research collaboration. The performance bonus is a discretionary bonus based upon our 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 August 31, 2012.

Under the terms of the agreement, all inventions created in connection with the activities performed under the agreement are our sole and exclusive property and all original works of authorship made by Professor Pellicciari that are protectable by copyright are works made for hire. Professor Pellicciari has also assigned to us all rights, title and interest in all inventions and any other intellectual property rights created under the agreement from January 1, 2011 through the end of its term. Professor Pellicciari must provide timely written notice of any inventions that he develops during the term of the agreement.

The agreement has a term of one year. However, at our sole discretion, we may extend the term of the agreement by one additional year. 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 our research program with Servier on the same financial terms as our original consulting agreement with Professor Pellicciari. Either we or Professor Pellicciari may terminate the agreement in the event of a material breach by the other party that is not remedied within 30 days after receipt of written notice of such breach from the other party.

OCA, INT-767 and INT-777

On January 1, 2012, we entered into a consulting agreement with Professor Pellicciari to provide scientific guidance for our research program relating to OCA, INT-767 and INT-777 and to supervise and coordinate this research program.

The agreement provides that Professor Pellicciari will receive compensation at an annual rate of €100,000 for his services during the term of the agreement in quarterly installments of €25,000.

Under the terms of the agreement, all inventions created in connection with the activities performed under the agreement are our sole and exclusive property and all original works of authorship made by Professor Pellicciari that are protectable by copyright are works made for hire. Professor Pellicciari has also assigned to us all rights, title and interest in all inventions and any other intellectual property rights created under the agreement. Professor Pellicciari must provide timely written notice of any inventions that he develops during the term of the agreement.

The agreement has a term of one year. However, at our sole discretion, we may extend the term of the agreement by one additional year. Either we or Professor Pellicciari may terminate the agreement in the event of a material breach

by the other party that is not remedied within 30 days after receipt of written notice of such breach from the other party.

WIL Research Laboratories, LLC

On October 2, 2007, we entered into a master laboratory services agreement with WIL Research Laboratories, LLC, or WIL, to perform certain research and laboratory services. The agreement was amended on October 28, 2011.

On November 16, 2011, we finalized work orders with WIL for the FDA-required studies in mice and rats to investigate the presence or absence of carcinogenic potential of OCA. We have agreed to pay WIL an aggregate of $4.0 million for the studies, consisting of a combination of quarterly installment payments of

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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, we have agreed to pay such reasonable additional costs upon receipt of proper invoice. We anticipate that the studies will continue through completion, all milestones will be satisfied and that we will pay to WIL an aggregate of $4.0 million under this agreement.

Under the terms of the agreement, we own all work product and data prepared or generated by WIL in the course of its services, assuming our payment of all required amounts specified in the contract. We have no property rights in WIL s intellectual property.

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 we 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.

Commercialization

Given our stage of development, we have not yet established a commercial organization or distribution capabilities. In the United States and Europe, due to the rare nature of PBC and the limited options for treatment, patients suffering from PBC and their physicians often have a high degree of organization and are well informed, which may make it easier to identify target populations if and when OCA is approved. The market for the treatment of PBC is a specialty care market driven by key opinion leaders. Most patients with PBC are treated at a limited number of academic centers or otherwise by physicians who specialize in the treatment of liver disease. If OCA is approved for the treatment of patients with PBC, we believe that it will be possible to commercialize OCA for this indication with a relatively small specialty sales force that calls on a limited and focused group of physicians. Our current plan is to commercialize OCA for PBC ourselves in the United States and Europe if it is approved. We may build our own commercial infrastructure or utilize contract reimbursement specialists, sales people and medical education specialists, and take other steps to establish the necessary commercial infrastructure at such time as we believe that OCA is approaching marketing approval. Outside of the United States and Europe, subject to obtaining necessary marketing approvals, we likely will seek to commercialize OCA through distribution or other collaboration arrangements for PBC. As a result of our ongoing clinical work, we have been engaged in dialogue with specialists who treat patients with PBC. We believe that these activities have provided us with a growing knowledge of the physicians we plan to target for commercial launch of OCA for PBC, subject to marketing approval in the United States and Europe. In March 2011, we exclusively licensed rights to OCA to DSP in Japan and China, along with an option to expand this exclusive license into certain other Asian countries. If we pursue approval for OCA in more prevalent liver diseases such as NASH, we would plan to do so selectively either on our own or by establishing collaborations with one or more pharmaceutical companies.

Competition

The biopharmaceutical industry is characterized by intense competition and rapid innovation. Although we believe that we hold a leading position in bile acid chemistry, our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results. Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. We believe the key

competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety and tolerability profile, reliability, convenience of dosing, price and reimbursement.

Our most advanced product candidate, OCA, is currently being developed as a second line treatment for PBC. Currently, ursodiol is the only therapy that is approved for the treatment of PBC. Although there are currently no other drugs approved for the treatment of PBC, we are aware of other companies, including Eli Lilly, Exelixis, Inc. and Phenex Pharmaceuticals AG that have FXR agonists in Phase 1 or earlier stages of preclinical development that could be used to treat PBC and the other liver diseases we are targeting. In addition, Johnson & Johnson and NovImmune SA are each currently conducting Phase 2a proof-of-concept

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open label clinical trials of monoclonal antibodies as potential treatments for PBC. Finally, Dr. Falk Pharma GmbH, which markets ursodiol, is conducting a Phase 3 clinical trial of combination ursodiol and budesonide, a steroid, as a treatment for PBC.

For the treatment of portal hypertension, the only therapeutic products available are beta blockers, which clinical studies have shown are effective only in approximately 25% to 33% of patients, while having significant safety issues. We are aware of only one other company, Dr. Falk Pharma GmbH, which has a new product candidate in Phase 2 clinical development for the treatment of portal hypertension.

There are currently no therapeutic products approved for the treatment of NASH or NAFLD. There are several marketed therapeutics that are currently used off label for the treatment of NASH, such as insulin sensitizers (e.g., metformin), antihyperlipidemic agents (e.g., gemfibrozil), pentoxifylline and ursodiol, but none has been clearly shown in clinical trials to alter the course of the disease. We are aware of several companies that have product candidates in Phase 2 clinical development for the treatment of NASH, including Dr. Falk Pharma GmbH, Galmed Medical Research Ltd., Immuron Ltd., Mochida Pharmaceutical Co., Ltd., NasVax Ltd. and Raptor Pharmaceutical Corp., and there are other companies with candidates in earlier stage programs. In addition, it is possible that one or more of the FXR agonist product candidates mentioned above that are being developed by our competitors could be used for the treatment of NASH.

For the treatment of bile acid diarrhea, bile acid binding resins such as cholestyramine are currently used as the only available targeted therapy. Patients with this disease represent a subset of patients diagnosed with irritable bowel syndrome with diarrhea, or IBS-D, and we are aware of several companies with product candidates in Phase 2 or 3 clinical development for the treatment of IBS-D, including Astellas Pharma US, Inc., AstraZeneca, Salix Pharmaceuticals, Inc. and Tioga Pharmaceuticals, Inc. In addition, there are several marketed products indicated for the treatment of IBS-D, including GlaxoSmithKline s Lotronex and the over-the-counter product Immodium.

We believe that OCA offers key potential advantages over ursodiol and other products in development that could enable OCA, if approved for these indications, to capture meaningful market share. However, many of our potential competitors have substantially greater financial, technical and human resources than we do, as well as greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products. Accordingly, our competitors may be more successful than us in obtaining approval from the FDA or from other regulators for drugs and achieving widespread market acceptance. Our competitors drugs may be more effective, or more effectively marketed and sold, than any product candidate we may commercialize and may render our product candidates obsolete or non-competitive before we can recover the expenses of their development and commercialization. We anticipate that we will face intense and increasing competition as new drugs enter the market and other advanced technologies become available. Finally, the development of new treatment methods for the diseases we are targeting could render our product candidates non-competitive or obsolete.

Intellectual Property

The proprietary nature of, and protection for, our product candidates and our discovery programs, processes and know-how are important to our business. We have sought patent protection in the United States and internationally for OCA, INT-767 and INT-777, and our discovery programs, and any other inventions to which we have rights, where available and when appropriate. Our policy is to pursue, maintain and defend patent rights, whether developed internally or licensed from third parties, and to protect the technology, inventions and improvements that are commercially important to the development of our business. We also rely on trade secrets that may be important to the

development of our business.

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 develop and 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 products depends on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our product

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candidates, discovery programs and processes. For this and more comprehensive risks related to our intellectual property, please see Risk Factors Risks Relating to Our Intellectual Property.

OCA (formerly called INT-747) (first-in-class FXR agonist)

The patent portfolio for OCA contains patents and patent applications directed to compositions of matter, manufacturing methods, and methods of use. As of August 31, 2012, we owned four U.S. patents, three pending U.S. patent applications, and corresponding foreign patents and patent applications. Foreign patents have been granted in Europe, Norway, Spain, Denmark, Germany, Austria, Australia, Japan, Canada, Belgium, Cyprus, Finland, France, Greece, Ireland, Israel, Italy, Luxembourg, Monaco, Netherlands, Portugal, Sweden, Switzerland, Turkey and the United Kingdom. We expect the composition of matter patent, if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire in 2022 (worldwide). It is possible that the term of the composition of matter patent in the United States may be extended up to five additional years under the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act. Patent term extension may be available in certain foreign countries upon regulatory approval. We expect the other patents and patent applications in the portfolio, if issued, and if the appropriate maintenance, renewal, annuity, or other governmental fees are paid, to expire from 2022 to 2028.

INT-767 (dual FXR/TGR5 agonist)

The patent portfolio for INT-767 contains a patent and patent applications directed to compositions of matter and methods of use. As of August 31, 2012, we owned one U.S. patent, one pending U.S. patent application, and corresponding foreign patent applications have been filed in Australia, Canada, China, Europe, India, Israel, Japan and Hong Kong. We expect the issued composition of matter patent in the U.S., if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire in 2029. It is possible that the term of the composition of matter patent in the United States may be extended up to five additional years under the provisions of the Hatch-Waxman Act. We expect the pending foreign patent applications in the portfolio, if issued, and if the appropriate maintenance, renewal, annuity, or other governmental fees are paid, to expire in 2027. Patent term extension may be available in certain foreign countries upon regulatory approval. We have received assignments of rights to the INT-767 patent portfolio from all inventors, other than one inventor. That inventor is contractually obligated to provide an assignment to us. We believe that we are the owner of the INT-767 patent portfolio by virtue of this contractual obligation and the other patent assignments we have received.

INT-777 (TGR5 agonist)

The patent portfolio for INT-777 contains a patent and patent applications directed to compositions of matter and methods of use. As of August 31, 2012, we owned one U.S. patent, two pending U.S. patent applications, and corresponding foreign patent applications have been filed in Australia, Brazil, Canada, China, Eurasia, Europe, India, Israel, Japan, Korea, Mexico, Singapore, South Africa and Hong Kong. We expect the composition of matter patent in the United States, if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire in 2030. It is possible that the term of the composition of matter patent in the United States may be extended up to five additional years under the provisions of the Hatch-Waxman Act. We expect the corresponding foreign patent applications and other patent applications in the portfolio, if issued, and if the appropriate maintenance, renewal, annuity, or other governmental fees are paid, to expire from 2028 to 2029. Patent term extension may be available in certain foreign countries upon regulatory approval.

Trade Secrets

In addition to patents, we rely on trade secrets and know-how to develop and maintain our competitive position. Trade secrets and know-how can be difficult to protect. We seek to protect our proprietary processes, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and commercial partners. These agreements are designed to protect our proprietary information. We also seek to preserve the integrity and confidentiality of our data, trade secrets and know-how by maintaining physical security of our premises and physical and electronic security of our information technology systems.

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Manufacturing

We do not own or operate manufacturing facilities for the production of any of our product candidates, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently rely on third-party contract manufacturers for all of our required raw materials, active pharmaceutical ingredient, or API, and finished product for our preclinical research and clinical trials, including the Phase 3 trials for OCA for the treatment of PBC. We have also contracted with a back-up manufacturer for API. We do not have long-term agreements with any of these third parties. We also do not have any current contractual relationships for the manufacture of commercial supplies of any of our product candidates if they are approved. If any of our products are approved by any regulatory agency, we intend to enter into agreements with a third-party contract manufacturer and one or more back-up manufacturers for the commercial production of those products. Development and commercial quantities of any products that we develop will need to be manufactured in facilities, and by processes, that comply with the requirements of the FDA and the regulatory agencies of other jurisdictions in which we are seeking approval. We currently employ internal resources to manage our manufacturing contractors.

Government Regulation and Product Approval

Governmental authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, packaging, promotion, storage, advertising, distribution, marketing and export and import of products such as those we are developing. Our product candidates must be approved by the FDA through the NDA process before they may be legally marketed in the United States and by the EMA through the MAA process before they may be legally marketed in Europe. Our product candidates will be subject to similar requirements in other countries prior to marketing in those countries. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

United States Government Regulation

NDA Approval Processes

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and implementing regulations. Failure to comply with the applicable U.S. requirements at any time during the product development process or approval process, or after approval, may subject an applicant to administrative or judicial sanctions, any of which could have a material adverse effect on us. These sanctions could include:

refusal to approve pending applications;
withdrawal of an approval;
imposition of a clinical hold;
warning letters;
product seizures;
total or partial suspension of production or distribution; or
injunctions, fines, disgorgement, or civil or criminal penalties.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

completion of nonclinical laboratory tests, animal studies and formulation studies conducted according to Good

Laboratory Practices, or GLPs, or other applicable regulations;

submission to the FDA of an IND, which must become effective before human clinical trials may begin;

performance of adequate and well-controlled human clinical trials according to Good Clinical Practices, or GCPs, to establish the safety and efficacy of the proposed drug for its intended use;

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submission to the FDA of an NDA;
satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current Good Manufacturing Practices, or cGMPs, to assure that the facilities, methods and controls are adequate to preserve the drug s identity, strength, quality and purity; and
FDA review and approval of the NDA.

Once a pharmaceutical candidate is identified for development, it enters the preclinical or nonclinical testing stage. Nonclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit the results of the nonclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND. Some nonclinical testing may continue even after the IND is submitted. In addition to including the results of the nonclinical studies, the IND will also include a protocol detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the first phase lends itself to an efficacy determination. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the IND on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin. A clinical hold may occur at any time during the life of an IND, and may affect one or more specific studies or all studies conducted under the IND.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCPs. They must be conducted under protocols detailing the objectives of the trial, dosing procedures, research subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and progress reports detailing the status of the clinical trials must be submitted to the FDA annually. Sponsors also must timely report to FDA serious and unexpected adverse reactions, any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigation brochure, or any findings from other studies or animal or in vitro testing that suggest a significant risk in humans exposed to the drug. An institutional review board, or IRB, at each institution participating in the clinical trial must review and approve the protocol before a clinical trial commences at that institution and must also approve the information regarding the trial and the consent form that must be provided to each research subject or the subject s legal representative, monitor the study until completed and otherwise comply with IRB regulations.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

Phase 1. The drug is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and elimination. In the case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be inherently too toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
Phase 2. Clinical trials are performed on a limited patient population intended to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These studies are intended to establish the overall risk-benefit ratio of the product and provide an adequate basis for product labeling.

Human clinical trials are inherently uncertain and Phase 1, Phase 2 and Phase 3 testing may not be successfully completed. The FDA or the sponsor may suspend a clinical trial at any time for a variety of reasons, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB s requirements or if the drug has been associated with unexpected serious harm to patients.

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During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to the submission of an IND, at the end of Phase 2 and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date and for the FDA to provide advice on the next phase of development. Sponsors typically use the meeting at the end of Phase 2 to discuss their Phase 2 clinical results and present their plans for the pivotal Phase 3 clinical trial that they believe will support the approval of the new drug. If a Phase 2 clinical trial is the subject of discussion at the end of Phase 2 meeting with the FDA, a sponsor may be able to request a Special Protocol Assessment, or SPA, the purpose of which is to reach agreement with the FDA on the Phase 3 clinical trial protocol design and analysis that will form the primary basis of an efficacy claim.

According to published guidance on the SPA process, a sponsor which meets the prerequisites may make a specific request for a SPA and provide information regarding the design and size of the proposed clinical trial. The FDA is supposed to evaluate the protocol within 45 days of the request to assess whether the proposed trial is adequate, and that evaluation may result in discussions and a request for additional information. A SPA request must be made before the proposed trial begins, and all open issues must be resolved before the trial begins. If a written agreement is reached, it will be documented and made part of the record. The agreement will be binding on the FDA and may not be changed by the sponsor or the FDA after the trial begins except with the written agreement of the sponsor and the FDA or if the FDA determines that a substantial scientific issue essential to determining the safety or efficacy of the drug was identified after the testing began.

Concurrent with clinical trials, sponsors usually complete additional animal safety studies and also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing commercial quantities of the product in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug and the manufacturer must develop methods for testing the quality, purity and potency of the drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its proposed shelf-life.

The results of product development, nonclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests and other control mechanisms, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of user fees, but a waiver of such fees may be obtained under specified circumstances. The FDA reviews all NDAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. It may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing.

Once the submission is accepted for filing, the FDA begins an in-depth review. NDAs receive either standard or priority review. A drug representing a significant improvement in treatment, prevention or diagnosis of disease may receive priority review. The FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data. Even if such data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant. The FDA may refer the NDA to an advisory committee for review and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured and tested.

Expedited Review and Approval

The FDA has various programs, including Fast Track, priority review, and accelerated approval, which are intended to expedite or simplify the process for reviewing drugs, and/or provide for the approval of a drug on the basis of a surrogate endpoint. Even if a drug qualifies for one or more of these programs, the FDA may later decide that the drug no longer meets the conditions for qualification or that the time period for FDA

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review or approval will be shortened. Generally, drugs that are eligible for these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs and those that offer meaningful benefits over existing treatments. For example, Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious or life-threatening diseases or conditions and fill unmet medical needs. Priority review is designed to give drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists an initial review within six months as compared to a standard review time of ten months. Although Fast Track and priority review do not affect the standards for approval, the FDA will attempt to facilitate early and frequent meetings with a sponsor of a Fast Track designated drug and expedite review of the application for a drug designated for priority review. Accelerated approval, which is described in Subpart H of 21 CFR Part 314, provides for an earlier approval for a new drug that is intended to treat a serious or life-threatening disease or condition and that fills an unmet medical need based on a surrogate endpoint. A surrogate endpoint is a laboratory measurement or physical sign used as an indirect or substitute measurement representing a clinically meaningful outcome. As a condition of approval, the FDA may require that a sponsor of a drug candidate receiving accelerated approval perform post-marketing clinical trials.

In the recently enacted Food and Drug Administration Safety and Innovation Act, or FDASIA, Congress encouraged the FDA to utilize innovative and flexible approaches to the assessment of products under accelerated approval. The law requires the FDA to issue related draft guidance within a year after the law s enactment and also promulgate confirming regulatory changes.

We currently plan to seek accelerated approval of OCA for the treatment of PBC assuming satisfactory achievement of a surrogate endpoint in our Phase 3 POISE trial that we believe is reasonably likely to predict clinical benefit. We also intend to have commenced a second Phase 3 trial to confirm clinical benefit at the time of the NDA submission which we plan to complete on a post-marketing basis if the NDA is approved.

Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of the use of our drug candidates, some of our U.S. patents may be eligible for limited patent term extension 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, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product s approval date. The patent term restoration period is generally one-half the time between the effective date of an IND, and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for extension must be made prior to expiration of the patent. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we intend to apply for restorations of patent term for some of our currently owned or licensed patents to add patent life beyond their current expiration date, depending on the expected length of clinical trials and other factors involved in the submission of the relevant NDA.

Market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an

application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an approved NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing

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the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication, except in very limited circumstances, for seven years. Orphan drug exclusivity, however, could also block the approval of one of our products for seven years if a competitor obtains approval of the same drug as defined by the FDA or if our drug candidate is determined to be contained within the competitor s product for the same indication or disease.

Pediatric Exclusivity and Pediatric Use

Under the Best Pharmaceuticals for Children Act, or BPCA, certain drugs may obtain an additional six months of exclusivity, if the sponsor submits information requested in writing by the FDA, or a Written Request, relating to the use of the active moiety of the drug in children. The FDA may not issue a Written Request for studies on unapproved or approved indications or where it determines that information relating to the use of a drug in a pediatric population, or part of the pediatric population, may not produce health benefits in that population.

We have not received a Written Request for such pediatric studies, although we may ask the FDA to issue a Written Request for such studies in the future. To receive the six-month pediatric market exclusivity, we would have to receive a Written Request from the FDA, conduct the requested studies in accordance with a written agreement with the FDA or, if there is no written agreement, in accordance with commonly accepted scientific principles, and submit reports of the studies. A Written Request may include studies for indications that are not currently in the labeling if the FDA determines that such information will benefit the public health. The FDA will accept the reports upon its determination that the studies were conducted in accordance with and are responsive to the original Written Request or commonly accepted scientific principles, as appropriate, and that the reports comply with the FDA s filing requirements.

In addition, the Pediatric Research Equity Act, or PREA, requires a sponsor to conduct pediatric studies for most drugs and biologicals, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs, biologics license application and supplements thereto, must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric studies for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug or biologic is ready for approval for use in adults before

pediatric studies are complete or that additional safety or effectiveness data needs to be collected before the pediatric studies begin. After April 2013, the FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

As part of the FDASIA, Congress made a few revisions to BPCA and PREA, which were slated to expire on September 30, 2012, and made both laws permanent.

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Post-approval Requirements

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products that have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs.

Any drug products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things:

record-keeping requirements;
reporting of adverse experiences with the drug;
providing the FDA with updated safety and efficacy information;
drug sampling and distribution requirements;
notifying the FDA and gaining its approval of specified manufacturing or labeling changes; and
complying with FDA promotion and advertising requirements.

Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and some state agencies for compliance with cGMP and other laws.

We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products. Future FDA and state inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

Regulation Outside of the United States

In addition to regulations in the United States, we will be subject to regulations of other countries governing clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain approval by the comparable regulatory authorities of countries outside of the United States before we can commence clinical trials in such countries and approval of the regulators of such countries or economic areas, such as the European Union, before we may market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

Under European Union regulatory systems, a company may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure, which is compulsory for medicines produced by biotechnology or those medicines intended to treat AIDS, cancer, neurodegenerative disorders or diabetes and

optional for those medicines which are highly innovative, provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessments report, each member state must decide whether to recognize

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approval. If a member state does not recognize the marketing authorization, the disputed points are eventually referred to the European Commission, whose decision is binding on all member states.

As in the United States, we may apply for designation of a product as an orphan drug for the treatment of a specific indication in the European Union before the application for marketing authorization is made. Orphan drugs in Europe enjoy economic and marketing benefits, including up to ten years of market exclusivity for the approved indication unless another applicant can show that its product is safer, more effective or otherwise clinically superior to the orphan-designated product.

ATU

We may apply to make OCA available for use under a cohort Autorisation Temporaire d Utilisation, or Temporary Authorization for Use, or ATU, in France. Under an ATU, the French Health Products Safety Agency, or Afssaps, allows the use of a drug in France before marketing approval has been obtained in France in order to treat serious or rare diseases for which no other treatment is available in that country. Afssaps will only grant an ATU where the benefit of the product outweighs the risk. An ATU is granted for one year and may be renewed. If an ATU is granted for OCA, we will be required to gather and analyze data concerning OCA s use and submit a periodic report to Afssaps. We also will be responsible for submitting pharmacovigilance reports, as necessary. An ATU may be modified, suspended, or withdrawn for reasons of public health or if the conditions under which the ATU was granted are no longer met. We believe the granting of an ATU and subsequent use by patients in France prior to marketing approval may enable us to begin recognizing some product sales revenue for OCA prior to its approval in the United States and the remainder of the European Union.

Reimbursement

Sales of our products will depend, in part, on the extent to which the costs of our products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly challenging the prices charged for medical products and services. Additionally, the containment of healthcare costs has become a priority of federal and state governments and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. If these third-party payors do not consider our products to be cost-effective compared to other therapies, they may not cover our products after approved as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, imposed new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities which will provide coverage of outpatient prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Part A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government

payment for some of the costs of prescription drugs may increase demand for our products for which we receive marketing approval. However, 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.

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The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. A plan for the research will be developed by the Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures will be made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of any product, if any such product or the condition that it is intended to treat is the subject of a study. It is also possible that comparative effectiveness research demonstrating benefits in a competitor s product could adversely affect the sales of our product candidates. If third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, collectively referred to as the ACA, enacted in March 2010, is expected to have a significant impact on the health care industry. ACA is expected to expand coverage for the uninsured while at the same time containing overall healthcare costs. With regard to pharmaceutical products, among other things, ACA is expected to expand and increase industry rebates for drugs covered under Medicaid programs and make changes to the coverage requirements under the Medicare Part D program. We cannot predict the impact of ACA on pharmaceutical companies, as many of the ACA reforms require the promulgation of detailed regulations implementing the statutory provisions which has not yet occurred. 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. These challenges add to the uncertainty of the legislative changes enacted as part of ACA.

In addition, in some non-U.S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally tend to be significantly lower.

Legal Proceedings

We are not currently a party to any material legal proceedings.

Facilities

Our corporate headquarters and clinical development operations are located in New York, New York and San Diego, California, where we lease and occupy approximately 3,500 and 7,600 square feet of space, respectively. The leases for our New York office and our San Diego office expire in November 2013 and December 2014, respectively. We believe that our facilities are suitable and adequate for our current needs.

Employees

As of August 31, 2012, we had 18 employees, of which 14 are involved in our drug development operations and four are in general and administrative functions. None of our employees are represented by a labor union and we consider our employee relations to be good.

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MANAGEMENT

Executive Officers and Directors

The following table sets forth certain information about our executive officers and directors and our director nominee as of September 26, 2012:

Name	Age	Position(s)
Executive Officers:		
Mark Pruzanski, M.D.	44	President and Chief Executive Officer, and Director
David Shapiro, M.D.	58	Chief Medical Officer and Executive Vice President, Development
Barbara Duncan	47	Chief Financial Officer, Secretary and Treasurer
Luciano Adorini, M.D.	63	Chief Scientific Officer
Non-Employee Directors and Director Nominee:		
Lorenzo Tallarigo, M.D.(2)	61	Chairman of the Board
Paolo Fundaro(1)(3)	38	Director
Jonathan Silverstein(1)(3)	45	Director
Klaus Veitinger, M.D.(2)	50	Director
Nicole Williams(1)(2)(3)	68	Director
Srinivas Akkaraju, M.D., Ph. D.(4)	44	Director Nominee

(1) Member of our audit committee

(2) Member of our compensation committee

(3) Member of our nominating and governance committee

(4) In September 2012, Dr. Akkaraju was appointed by our board of directors, effective upon the completion of this offering, to fill the vacancy on our board of directors. Dr. Akkaraju will be assigned to the various committees of our board of directors after the completion of this offering.

Executive Officers

Mark Pruzanski, M.D. is a co-founder of the company and has served as our chief executive officer and president, and has been a member of our board of directors, since our inception in 2002. He has over 15 years of experience in life sciences company management, venture capital and strategic consulting. Dr. Pruzanski was previously a venture partner at Apple Tree Partners, an early stage life sciences venture capital firm he co-founded in 1999. Prior to that, he was an entrepreneur-in-residence at Oak Investment Partners. Dr. Pruzanski received his M.D. from McMaster University in Ontario, a M.A. degree in International Affairs from the Johns Hopkins University School of Advanced International Studies in Bologna, Italy and Washington, D.C., and a bachelor s degree from McGill University in Montreal, Quebec. He currently also serves on the boards of the Emerging Company Section of the Biotechnology Industry Association (BIO) and the Foundation for the Defense of Democracies, a think tank in Washington, D.C. Dr. Pruzanski is a co-author of a number of scientific publications and an inventor of several patents relating to our product candidates and scientific discoveries.

We believe that Dr. Pruzanski s perspective and the experience he brings as our chief executive officer and president and as one of our company s founders, together with his historic knowledge of our company and our product

candidates, operational expertise and continuity to our board of directors, and his experience in managing and investing in companies within the life sciences industry, qualify him to serve as a member of our board of directors.

David Shapiro, M.D. has served as our chief medical officer and executive vice president, development since 2008. He has over 25 years of clinical development experience in the pharmaceutical industry. Dr. Shapiro founded a consulting company, Integrated Quality Resources, that focused on development stage biopharmaceutical companies and was active in this role from 2005 to 2008. From 2000 to 2005, Dr. Shapiro was executive vice president, medical affairs and chief medical officer of Idun

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Pharmaceuticals, Inc., prior to its acquisition by Pfizer. From 1995 to 1998, he was president of the Scripps Medical Research Center at Scripps Clinic. He also served as vice president, clinical research at Gensia and as director and group leader, hypertension clinical research at Merck Research Laboratories from 1985 to 1990. Dr. Shapiro has authored more than 20 peer-reviewed publications and organized and chaired several conferences aimed at improving product development. He received his medical degree from Dundee University & Medical School, and undertook his postgraduate medical training in the university affiliated hospitals in Oxford, United Kingdom and the University of Vermont. Dr. Shapiro served on the board of directors of Altair Therapeutics and served for two terms on the Executive Committee of the Board of the American Academy of Pharmaceutical Physicians. He is an elected Fellow of both the Royal College of Physicians of London and the Faculty of Pharmaceutical Physicians of the United Kingdom.

Barbara Duncan has served as our chief financial officer and secretary since May 2009 and as our treasurer since 2010. She has over 14 years experience in the life sciences industry. From 2001 through April 2009, Ms. Duncan served as chief financial officer and then chief executive officer at DOV Pharmaceutical, Inc., or DOV, a biopharmaceutical company focused on central nervous system disorders, which was sold to Euthymics Bioscience, Inc. in 2010. Prior to joining DOV, Ms. Duncan served as a vice president of Lehman Brothers Inc. in its corporate finance division from August 1998 to August 2001, where she provided financial advisory services primarily to companies in the life sciences and general industrial industries. From September 1994 to August 1998, Ms. Duncan was an associate and director at SBC Warburg Dillon Read, Inc. in its corporate finance group, where she focused primarily on structuring mergers, divestitures and financings for companies in the life sciences and general industrial industries. She also worked for PepsiCo, Inc. from 1989 to 1992 in its international audit division, and was a certified public accountant in the audit division of Deloitte & Touche LLP from 1986 to 1989. Ms. Duncan received her B.S. from Louisiana State University in 1985 and her M.B.A. from the Wharton School, University of Pennsylvania, in 1994. She previously served as a director of DOV and currently serves on the board of directors of Edgemont Pharmaceuticals, LLC, a privately held, specialty pharmaceutical company with a primary focus in the field of neuroscience.

Luciano Adorini, M.D. has served as our chief scientific officer since 2008. Dr. Adorini has over 20 years of industry experience. From January 2002 through December 2007, Dr. Adorini served as chief scientific officer at BioXell S.p.A., where he was responsible for advancing a broad pipeline of products in multiple disease indications. From January 1993 to December 2001, he served as associate director of Roche Milano Richerche, where he contributed to the development of several drugs. Earlier in his career, Dr. Adorini was research director of a unit at the Preclinical Research Center, Sandoz Pharma, Ltd., in Basel, Switzerland. Dr. Adorini has authored over 280 journal articles and other scientific publications, becoming a highly cited researcher in immunology, with a focus on immunosuppressive and immunoregulatory mechanisms in the treatment of inflammatory and autoimmune diseases. He is a board member of a number of peer-reviewed publications and has served as president of the Italian Society of Immunology, Clinical Immunology and Allergology. Dr. Adorini received his M.D. degree from the Medical School of Padova University and conducted postdoctoral studies at the University of California at Los Angeles.

Non-Employee Directors and Director Nominee

Lorenzo Tallarigo, M.D. has served as a member of our board of directors since 2008 and is our chairman. Since 2009, he has been the chief executive officer of Genextra S.p.A., our principal stockholder. Dr. Tallarigo joined Eli Lilly Pharmaceuticals in 1985 and held various positions in areas of clinical research, pharmaceutical product management and marketing and general management, most recently as its president of international operations until 2008. Dr. Tallarigo is a member of the board of directors of Genextra S.p.A. Dr. Tallarigo received a doctor of medicine degree from the University of Pisa in Italy.

We believe that Dr. Tallarigo s significant experience in various senior management roles in the biopharmaceutical industry and his experience investing in and growing companies in various industries, including the biopharmaceutical industry, qualify him to serve as a member of our board of directors.

Paolo Fundaro has served as a member of our board of directors since 2006. Mr. Fundaro has been Genextra s chief financial officer since its inception in 2004. Before joining Genextra, Mr. Fundaro was director of finance and strategic planning for the Fastweb Group from 2000 to 2004. Previously, he worked

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for investment banks, including Salomon Smith Barney (now Citigroup) and Donaldson Lufkin & Jenrette (now Credit Suisse). Mr. Fundaro has a degree in Business Management from the Bocconi University in Milan.

We believe that Mr. Fundaro possesses specific attributes that qualify him to serve as a member of our board of directors, including his significant experience in corporate finance and his experience building, investing in and growing companies in diverse industries, including the biopharmaceutical industry.

Jonathan Silverstein has served as a member of our board of directors since August 2012. Since 1998, Mr. Silverstein has been a member of OrbiMed Advisors LLC, an asset management firm solely focused in healthcare with several billion dollars in assets under management. Prior to OrbiMed, Mr. Silverstein was a director of life sciences in the investment banking department at Sumitomo Bank. Mr. Silverstein currently serves on the board of directors of a number of private companies. From 2008 until 2011, Mr. Silverstein was a director of NxStage Medical, Inc. From 2006 until 2008, Mr. Silverstein was a director of Insulet, Inc. From 2004 until 2007, Mr. Silverstein was a director of Avanir Pharmaceuticals, Inc. Mr. Silverstein has a B.A. in economics from Denison University and a J.D. and M.B.A. from the University of San Diego. Our board of directors appointed Mr. Silverstein to the board in connection with the Series C preferred stock financing.

We believe that Mr. Silverstein brings leadership, strategic, small company build-up and capital market experience, particularly within the life science sector, to our board of directors.

Klaus Veitinger, M.D., has served as a member of our board of directors since August 2012. Since October 2007, Dr. Veitinger has been a venture partner at OrbiMed Advisors LLC, an asset management firm solely focused in healthcare with several billion dollars in assets under management. Prior to joining OrbiMed Advisors LLC, Dr. Veitinger was employed at Schwarz Pharma AG from 1990 until its acquisition by UCB S.A. in December 2006, where he held various positions in areas of general management, drug development, licensing and business development, strategic planning and mergers and acquisitions, including most recently as the chief executive officer of U.S. and Asian operations and as a member of the executive board. Dr. Veitinger currently serves on, and has previously served on, the board of directors of numerous private companies and several public companies. Dr. Veitinger earned his medical degree from the University of Heidelberg and has a U.S. medical certification. He earned his doctorate (Ph.D.) in pathophysiology from the University of Heidelberg and his M.B.A. at INSEAD in France. Our board of directors appointed Dr. Veitinger to the board in connection with the Series C preferred stock financing.

We believe that Dr. Veitinger possesses specific attributes that qualify him to serve as a member of our board of directors, including his significant experience in corporate strategy, drug development, regulatory and commercial matters, as well as his experience in general management of biopharmaceutical companies.

Nicole Williams has served as a member of our board of directors since 2008. Ms. Williams has 17 years experience as a chief financial officer of public and private global companies. Ms. Williams formerly was the chief financial officer of Abraxis Bioscience Inc., a biopharmaceutical company, and president of Abraxis Pharmaceutical Products, a division of Abraxis Bioscience Inc., positions she assumed upon the merger of American Pharmaceutical Partners, Inc. and American Bioscience Inc. in April 2006. From 2002 to 2006, Ms. Williams was the executive vice president and chief financial officer of American Pharmaceutical Partners and in December 2005, assumed additional responsibilities as president of American Pharmaceutical Partners. Ms. Williams is the President of the Nicklin Capital Group, Inc., a firm she founded in 1999 that invests in and provides consulting to early stage technology companies in the Midwest United States. From 1992 to 1999, Ms. Williams was the executive vice president, chief financial officer and corporate secretary of R.P. Scherer Corporation in Troy, Michigan. She currently serves as a director and audit committee chair of Progenics Pharmaceuticals, Inc. and previously held the same positions at Orchid Cellmark, Inc., a leading DNA identity testing service company, until its acquisition in 2011 by Laboratory Corporation of America

Holdings. In 2007, she earned a Certificate of Director Education from the National Association of Corporate Directors. Ms. Williams received her Demi-License es Science Politique from the University of Geneva, Switzerland, her License es Science Politique from the Graduate Institute of International Affairs, University of Geneva, Switzerland and her M.B.A. from the Graduate School of Business, University of Chicago.

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We believe that Ms. Williams financial expertise, her experience with operations and her service as a chief financial officer and board member with other companies qualify her to serve as a member of our board of directors. In addition, she brings expertise to the company in the areas of financial analysis and reporting, internal auditing and controls and risk management oversight. Her board and audit committee roles at other public companies give her a broad perspective in the areas of financial reporting and audit and enterprise risk management.

Srinivas Akkaraju, M.D., Ph.D. was appointed by our board of directors in September 2012 to fill the vacancy on our board of directors, effective upon the completion of this offering. Since 2009, Dr. Akkaraju has been a managing director of New Leaf Venture Partners, L.L.C. From 2006 to 2008, Dr. Akkaraju served as a managing director at Panorama Capital, LLC, a private equity firm founded by the former venture capital investment team of J.P. Morgan Partners, LLC, a private equity division of JPMorgan Chase & Co. Prior to co-founding Panorama Capital, he was with J.P. Morgan Partners, which he joined in 2001 and of which he became a partner in 2005. From 1998 to 2001, he was in business and corporate development at Genentech, Inc. (a wholly owned member of the Roche Group), a biotechnology company, most recently as senior manager. Prior to joining Genentech, Dr. Akkaraju was a graduate student at Stanford University, where he received an M.D. and a Ph.D. in Immunology. He received his undergraduate degrees in Biochemistry and Computer Science from Rice University. Dr. Akkaraju serves as a director Seattle Genetics, Inc. a publicly traded biotechnology company. Previously, Dr. Akkaraju served as a director on the boards of SynaGeva Biopharma Corp., Barrier Therapeutics, Inc. and Pharmos Inc., all of which are publicly traded biotechnology companies, and Amarin Corporation plc, a foreign publicly traded biotechnology company.

We believe that Dr. Akkaraju s scientific background, coupled with experience in private equity and venture capital investing from his work at New Leaf Venture Partners, J.P. Morgan and Panorama Capital, qualify him to serve as a member of our board of directors.

Composition of our Board of Directors

Upon the completion of this offering, our board of directors will consist of seven members, six of whom will be non-employee directors. The six members who currently serve on our board of directors were elected pursuant to the board composition provisions of our stockholders agreement, which provisions will terminate upon the completion of this offering. Upon termination of these provisions, there will be no further contractual obligations regarding the election of our directors.

In accordance with our restated certificate of incorporation and restated by-laws to be effective upon completion of this offering, our board of directors will be elected annually. Our directors hold office until their successors have been elected and qualified or until the earlier of their death, resignation or removal. There are no family relationships among any of our directors or executive officers. Our restated certificate of incorporation provides that the authorized number of directors comprising our board of directors shall be fixed by a majority of the total number of directors.

Director Independence

Under Rules 5605 and 5615 of the NASDAQ Marketplace Rules, a majority of a listed company s board of directors must be comprised of independent directors within one year of listing. In addition, NASDAQ Marketplace Rules require that, subject to specified exceptions, including certain phase-in rules, each member of a listed company s audit, compensation and governance and nominating committees be independent and that audit committee members also satisfy independence criteria set forth in Rule 10A-3 under the Exchange Act. Under Rule 5605(a)(2) of the NASDAQ Marketplace Rules, a director will only qualify as an independent director if, in the opinion of that company s board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in

carrying out the responsibilities of a director.

Based upon information requested from and provided by each director and our director nominee concerning their background, employment and affiliations, including family relationships, our board of directors has determined that all of our directors other than Dr. Pruzanski, our chief executive officer, and our director nominee, are independent under the applicable rules and regulations of the NASDAQ Stock Market. Our board of directors also determined that Drs. Veitinger and Tallarigo and Ms. Williams, who comprise our

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compensation committee; and Messrs. Fundaro and Silverstein and Ms. Williams, who comprise our nominating and governance committee, all satisfy the independence standards for such committees established by the Securities and Exchange Commission and the NASDAQ Marketplace Rules, as applicable. With respect to our audit committee, our board of directors has determined that Ms. Williams and Mr. Silverstein satisfy the independence standards for such committee established by Rule 10A-3 under the Exchange Act, the Securities and Exchange Commission and the NASDAQ Marketplace Rules, as applicable, but that Mr. Fundaro, the other member of the audit committee, does not satisfy all of these standards because of his relationship with Genextra, one of our affiliates. As such, we are relying upon the phase-in provisions of Rule 10A-3 and the rules of the NASDAQ Stock Market, as further described below in the description of our audit committee. In making such determinations, the board of directors considered the relationships that each such non-employee director or director nominee has with our company and all other facts and circumstances the board of directors deemed relevant in determining their independence.

Board Diversity

Upon completion of our initial public offering, our nominating and governance committee will be responsible for reviewing with the board of directors, on an annual basis, the appropriate characteristics, skills and experience required for the board of directors as a whole and its individual members. In evaluating the suitability of individual candidates (both new candidates and current members), the nominating and corporate governance committee, in recommending candidates for election, and the board of directors, in approving (and, in the case of vacancies, appointing) such candidates, will take into account many factors, including the following:

diversity of personal and professional background, perspective, experience, age, gender, ethnicity and country of citizenship;

personal and professional integrity and ethical values;

experience in one or more fields of business, professional, governmental, scientific or educational endeavors, and a general appreciation of major issues facing public companies similar in scope and size to us;

experience relevant to our industry or with relevant social policy concerns;

relevant academic expertise or other proficiency in an area of our operations;

objective and mature business judgment and expertise; and

any other relevant qualifications, attributes or skills.

Committees of the Board of Directors

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee. Each committee operates under a charter approved by our board of directors. Following the closing of this offering, copies of each committee s charter will be posted on the Investor Relations section of our website, which is located at *www.interceptpharma.com*. The composition and function of each of these committees are described below. Dr. Akkaraju, our director nominee, will be assigned to the various committees of our board of directors after the completion of this offering.

Audit Committee. Our audit committee is comprised of Ms. Williams and Messrs. Fundaro and Silverstein. Ms. Williams is the chairperson of the committee. Our board of directors has determined that Ms. Williams is an audit committee financial expert, as defined by the rules of the Securities and Exchange Commission, and satisfies the financial sophistication requirements of applicable NASDAQ rules.

Under the applicable NASDAQ rules, we are permitted to phase in our compliance with the independent audit committee requirements set forth in NASDAQ Marketplace Rule 5605(c)(2)(A)(ii) on the same schedule as we are permitted to phase in our compliance with the independent audit committee requirement pursuant to Rule

10A-3(b)(1)(iv)(A) under the Exchange Act, which require (1) one independent member at the time of listing; (2) a majority of independent members within 90 days of listing; and (3) all independent members within one year of listing.

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Our board of directors has determined that each of Ms. Williams and Mr. Veitinger is an independent director under the NASDAQ Marketplace Rules and Rule 10A-3 of the Exchange Act. Within one year of our listing on the NASDAQ Global Market, we expect that Mr. Fundaro will resign from our audit committee and be replaced with a new director who is independent under NASDAQ Marketplace Rule 5605(c)(2)(A)(ii) and Rule 10A-3.

Our audit committee is authorized to:

approve and retain the independent auditors to conduct the annual audit of our financial statements;
review the proposed scope and results of the audit;
review and pre-approve audit and non-audit fees and services;
review accounting and financial controls with the independent auditors and our financial and accounting staff;
review and approve transactions between us and our directors, officers and affiliates;
recognize and prevent prohibited non-audit services;
establish procedures for complaints received by us regarding accounting matters;
oversee internal audit functions, if any; and
prepare the report of the audit committee that the rules of the Securities and Exchange Commission require to be included in our annual meeting proxy statement.

Compensation Committee. Our compensation committee is comprised of Drs. Veitinger and Tallarigo and Ms. Williams. Dr. Veitinger is the chairman of the committee. Our compensation committee is authorized to:

review and recommend the compensation arrangements for management, including the compensation for our president and chief executive officer;
establish and review general compensation policies with the objective to attract and retain superior talent, to reward individual performance and to achieve our financial goals;
administer our stock incentive plans; and
prepare the report of the compensation committee that the rules of the Securities and Exchange Commission require to be included in our annual meeting proxy statement.

Nominating and Governance Committee. Our nominating and governance committee is comprised of Messrs. Fundaro and Silverstein and Ms. Williams. Mr. Fundaro is the chairman of the committee. Our nominating and governance committee is authorized to:

identify and nominate members of the board of directors;
develop and recommend to the board of directors a set of corporate governance principles applicable to our company; and
oversee the evaluation of our board of directors.

Compensation Committee Interlocks and Insider Participation

No member of our compensation committee has at any time been an employee of ours. None of our executive officers serves as a member of another entity s board of directors or compensation committee that has one or more executive officers serving as a member of our board of directors or compensation committee.

Code of Business Conduct and Ethics

We have adopted a code of business conduct and ethics that will apply to all of our employees, officers and directors, including those officers responsible for financial reporting. The code of business conduct and ethics will be available on our website at *www.interceptpharma.com* upon the completion of this offering. We expect that any amendments to the code, or any waivers of its requirements, will be disclosed on our website.

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Board Leadership Structure and Board s Role in Risk Oversight

The positions of chairman of the board and chief executive officer are presently separated at our company. We believe that separating these positions allows our chief executive officer to focus on our day-to-day business, while allowing our chairman of the board to lead the board of directors in its fundamental role of providing advice to, and independent oversight of, management. Our board of directors recognizes the time, effort and energy that the chief executive officer is required to devote to his position in the current business environment, as well as the commitment required to serve as our chairman, particularly as the board of directors oversight responsibilities continue to grow. Our board of directors also believes that this structure ensures a greater role for the independent directors in the oversight of our company and active participation of the independent directors in setting agendas and establishing priorities and procedures for the work of our board of directors. This leadership structure also is preferred by a significant number of our stockholders. Our board of directors believes its administration of its risk oversight function has not affected its leadership structure.

While our restated by-laws and corporate governance guidelines do not require that our chairman and chief executive officer positions be separate, our board of directors believes that having separate positions is the appropriate leadership structure for us at this time and demonstrates our commitment to good corporate governance.

Risk is inherent with every business, and how well a business manages risk can ultimately determine its success. We face a number of risks, including risks relating to product candidate development, technological uncertainty, dependence on collaborative partners and other third parties, uncertainty regarding patents and proprietary rights, comprehensive government regulations, having no commercial manufacturing experience, marketing or sales capability or experience and dependence on key personnel, as more fully discussed under Risk Factors in this prospectus. Management is responsible for the day-to-day management of risks we face, while our board of directors, as a whole and through its committees, has responsibility for the oversight of risk management. In its risk oversight role, our board of directors has the responsibility to satisfy itself that the risk management processes designed and implemented by management are adequate and functioning as designed.

Our board of directors is actively involved in oversight of risks that could affect us. This oversight is conducted primarily through committees of the board of directors, but the full board of directors has retained responsibility for general oversight of risks. Our board of directors satisfies this responsibility through full reports by each committee chair regarding the committee s considerations and actions, as well as through regular reports directly from officers responsible for oversight of particular risks within our company as our board of directors believes that full and open communication between management and the board of directors is essential for effective risk management and oversight.

Limitation of Directors and Officers Liability and Indemnification

The Delaware General Corporation Law authorizes corporations to limit or eliminate, subject to specified conditions, the personal liability of directors to corporations and their stockholders for monetary damages for breach of their fiduciary duties. Our restated certificate of incorporation to be effective upon the completion of this offering limit the liability of our directors to the fullest extent permitted by Delaware law.

We have obtained director and officer liability insurance to cover liabilities our directors and officers may incur in connection with their services to us. Our restated certificate of incorporation and restated by-laws to be effective upon

the completion of this offering also provide that we will indemnify and advance expenses to any of our directors and officers who, by reason of the fact that he or she is one of our officers or directors, is involved in a legal proceeding of any nature. We will repay certain expenses incurred by a director or officer in connection with any civil, criminal, administrative or investigative action or proceeding, including actions by us or in our name. Such indemnifiable expenses include, to the maximum extent permitted by law, attorney s fees, judgments, fines, ERISA excise taxes, penalties, settlement amounts and other expenses reasonably incurred in connection with legal proceedings. A director or officer will not receive indemnification if he or she is found not to have acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interest.

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We have entered into or plan to enter into indemnification agreements with each of our directors, certain of our officers and our director nominee, the form of which is attached as an exhibit to the registration statement of which this prospectus is a part. These agreements provide that we will, among other things, indemnify and advance expenses to our directors and officers for certain expenses, including attorneys fees, judgments, fines and settlement amounts incurred by any such person in any action or proceeding, including any action by us arising out of such person s services as our director or officer, or any other company or enterprise to which the person provides services at our request. We believe that these provisions and agreements are necessary to attract and retain qualified persons as directors and officers.

Such limitation of liability and indemnification does not affect the availability of equitable remedies. In addition, we have been advised that in the opinion of the Securities and Exchange Commission, indemnification for liabilities arising under the Securities Act is against public policy as expressed in the Securities Act and is therefore unenforceable.

There is no pending litigation or proceeding involving any of our directors, officers, employees or agents, or our director nominee, in which indemnification will be required or permitted. We are not aware of any threatened litigation or proceeding that may result in a claim for such indemnification.

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EXECUTIVE AND DIRECTOR COMPENSATION

Summary Compensation Table

The following table sets forth the compensation paid or accrued during the fiscal year ended December 31, 2011 to our chief executive officer and our two other highest paid executive officers as of December 31, 2011. We refer to these officers as our named executive officers.

Name and Principal Position	Salary ($)	Bonus[1] ($)	Option Awards[2] ($)	All Other Compensation ($)	Total ($)
Mark Pruzanski, M.D. *Chief Executive Officer and President*	364,000	147,420	319,325		830,745
David Shapiro, M.D. *Chief Medical Officer and Executive Vice President, Development*	363,998	83,720	104,233	12,000 [3]	563,951
Barbara Duncan Chief Financial Officer, Secretary and Treasurer	312,000	71,760	93,388		477,148

(1) Amounts represent cash bonuses earned in 2011, which were paid during 2012, based on achievement of performance goals and other factors deemed relevant by our board of directors and the compensation committee. Our 2011 company objectives were related primarily to clinical development and partnering achievements. However, the payment of bonuses to our named executive officers are subject to the discretion of the board of directors and the compensation committee.

(2) Amounts reflect the grant date fair value of option awards granted in 2011 in accordance with ASC Topic 718. For information regarding assumptions underlying the valuation of equity awards, see note 10 to our consolidated financial statements and the discussion under Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Estimates Valuation of Stock-Based Compensation and Warrant Liability Stock-Based Compensation included elsewhere in this prospectus. These amounts do not correspond to the actual value that will be recognized by the named executive officers. Each grant vests in monthly installments ending on October 13, 2015.

(3) Represents a monthly car allowance of $1,000 paid to Dr. Shapiro in 2011 under the terms of his employment agreement, described below.

Narrative to Summary Compensation Table

Employment Arrangements with Our Named Executive Officers

Mark Pruzanski, M.D. On May 15, 2006, we entered into an employment agreement with Dr. Pruzanski, our President and Chief Executive Officer. This employment agreement provided for an initial term of one year with automatic renewals each year thereafter unless terminated by either us or Dr. Pruzanski. Dr. Pruzanski s base salary was originally set at $300,000 per year, subject to annual review and increase (but not decrease), as determined by our board of directors or the compensation committee. Dr. Pruzanski s employment agreement also provides that he is eligible to receive an annual bonus payment of up to 35% of his annual base salary, based on achievement of certain

performance milestones identified by our board of directors in consultation with Dr. Pruzanski. Dr. Pruzanski s annual salary for 2011 was $364,000. For 2011, the board of directors, at its discretion, determined to use a maximum bonus target of 45% of annual base salary for Dr. Pruzanski. Dr. Pruzanski s 2011 bonus of $147,420 represents approximately 90% of his maximum bonus amount.

Dr. Pruzanski is also eligible to participate in our group benefits programs, including but not limited to medical, disability and life insurance, vacation and retirement plans, and a 401(k) plan sponsored by us. We have agreed to pay 100% of the health insurance premiums of Dr. Pruzanski and his spouse and other dependents and an annual life insurance premium of $10,000. During 2011, although we paid the premium for Dr. Pruzanski s participation in our group life insurance policy, which is available generally to all employees,

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we did not purchase or pay premiums for any individual life insurance policy for Dr. Pruzanski. We are also required to purchase short-term and long-term disability policies ensuring at least 60% of Dr. Pruzanski s base salary.

If Dr. Pruzanski terminates his employment with us or we terminate his employment for any reason, in addition to payment of accrued compensation and benefits, Dr. Pruzanski will be entitled to an amount equal to the prorated portion of the bonus, if any, that would have been payable to him.

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

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

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

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

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

Under Dr. Pruzanski s employment agreement, cause for termination shall be deemed to exist upon (a) a good faith finding by a majority of the members of the board (excluding Dr. Pruzanski) that (i) Dr. Pruzanski has engaged in dishonesty, willful misconduct or gross negligence, or (ii) Dr. Pruzanski has materially breached the employment agreement, and has failed to cure such conduct or breach within 30 days

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after his receipt of written notice from us, or (b) Dr. Pruzanski s conviction or entry of nolo contendere to any crime involving moral turpitude, fraud or embezzlement, or any felony. Under Dr. Pruzanski s employment agreement, good reason is defined as a material change in duties, position, responsibilities or reporting requirements, relocation of Dr. Pruzanski s place of employment by more than 50 miles from his principal residence or place of employment prior to such change or our material breach of the employment agreement.

David Shapiro, M.D. Effective April 1, 2008, we entered into an employment agreement with Dr. Shapiro, our Chief Medical Officer and Executive Vice President, Development. This employment agreement provides for an initial term of one year with automatic renewals each year thereafter unless terminated by either us or Dr. Shapiro. Dr. Shapiro s base salary was originally set at $350,000 per year, subject to annual review and increase (but not decrease), as determined by our board of directors or the compensation committee. Dr. Shapiro is also eligible to receive an annual bonus payment of up to 25% of his annual base salary, based on achievement of certain performance milestones identified by our board of directors in consultation with Dr. Shapiro and our chief executive officer. Dr. Shapiro s annual salary for 2011 was $363,998. Dr. Shapiro s 2011 bonus of $83,720 represents approximately 92% of his maximum bonus amount.

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

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

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

Receipt of the severance benefits described above is conditioned upon Dr. Shapiro entering into a severance agreement, including a release of claims, with us. Dr. Shapiro has acknowledged and agreed that the timing of payments may be modified by us to comply with Section 409A of the Code.

Under Dr. Shapiro s employment agreement, cause for termination shall be deemed to exist upon (a) a good faith finding by us that (i) Dr. Shapiro has engaged in dishonesty, willful misconduct or gross negligence, (ii) Dr. Shapiro has materially breached the employment agreement, or (iii) Dr. Shapiro has breached or threatened to breach his invention, non-disclosure and non-solicitation agreement, and has failed

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to cure such conduct or breach within 30 days after his receipt of written notice from us, or (b) Dr. Shapiro s conviction or entry of nolo contendere to any crime involving moral turpitude, fraud or embezzlement, or any felony. Under Dr. Shapiro s employment agreement, good reason is defined as a relocation of Dr. Shapiro s place of employment within six months after a change in control by more than 35 miles from his principal residence or more than 50 miles from his place of employment immediately prior to such change in control or our material breach of the employment agreement.

Barbara Duncan. On May 16, 2009, we entered into an employment agreement with Ms. Duncan, our Chief Financial Officer. Ms. Duncan s employment agreement provides for an initial term of one year with automatic renewals each year thereafter unless terminated by either us or Ms. Duncan. Ms. Duncan s base salary was originally set at $300,000 per year, subject to annual review and increase (but not decrease), as determined by our board of directors or the compensation committee. Ms. Duncan is also eligible to receive an annual bonus payment of up to 25% of her annual base salary, based on achievement of certain performance milestones identified by our board of directors in consultation with Ms. Duncan and our chief executive officer. Ms. Duncan s annual salary for 2011 was $312,000. Ms. Duncan s 2011 bonus of $71,760 represents approximately 92% of her maximum bonus amount.

Ms. Duncan is also eligible to participate in our group benefits programs, including but not limited to medical, disability and life insurance, vacation and retirement plans, and a 401(k) plan sponsored by us. We have agreed to pay 100% of the health insurance premiums of Ms. Duncan and 90% of the health insurance premiums of Ms. Duncan s spouse and dependants, so long as they are not covered by the policy of her spouse s employer.

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

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

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

change of control is in addition to the provisions contained in our equity incentive plans governing the vesting of equity awards upon a change of control. See Equity Incentive Plans below.

Receipt of the severance benefits described above is conditioned upon Ms. Duncan entering into a severance agreement, including a release of claims, with us. Ms. Duncan has acknowledged and agreed that the timing of payments may be modified by us to comply with Section 409A of the Code.

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

Non-Competition, Confidential Information and Assignment of Inventions Agreements

Dr. Pruzanski is a party to a non-competition and non-solicitation agreement with us, dated as of June 20, 2006, which prevents him from competing with us or soliciting our employees or independent contractors during his employment and for a one-year period thereafter. In addition, each of our named executive officers has also entered into a standard form agreement with respect to confidential information and assignment of inventions. Among other things, this agreement obligates each named executive officer to refrain from disclosing any of our proprietary information received during the course of employment and to assign to us any inventions conceived or developed during the course of employment.

Outstanding Equity Awards at Fiscal Year-End

The following table presents the outstanding equity awards held by each of the named executive officers as of December 31, 2011.

Name	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable		Option Exercise Price ($)	Option Expiration Date
Mark Pruzanski	8,653	0		2.89	06/30/2014
	25,961	0		2.89	01/01/2015
	129,803	3	(1)	9.83	07/18/2016
	33,398	7,707	(2)	9.83	09/18/2018
	125,480	125,480	(3)	8.67	07/20/2020
	11,461	34,403	(4)	8.67	10/13/2021
David Shapiro	8,653	0		10.41	01/08/2018
	79,326	7,211	(6)	10.41	04/01/2018
	27,259	27,259	(3)	8.67	07/20/2020
	3,741	11,229	(4)	8.67	10/13/2021
Barbara Duncan	55,889	30,648	(5)	9.83	05/18/2019
	23,797	23,797	(3)	8.67	07/20/2020
	3,351	10,061	(4)	8.67	10/13/2021

(1) These options were fully vested as of January 31, 2012.

(2) These options will vest monthly through September 30, 2012.

(3) Options vest monthly through December 31, 2013.

(4) Options vest monthly through December 31, 2014.

(5) These options were fully vested as of May 31, 2012.

(6) These options were fully vested as of January 31, 2012.

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On September 13, 2012, our board of directors authorized the grant of the following equity awards to our named executive officers:

Name	Stock Options	Restricted Stock Units
Mark Pruzanski	51,922	77,884
David Shapiro	17,307	25,961
Barbara Duncan	13,846	20,769

These grants will be made on the 31st day after the completion of this offering, or the issuance date, with the exercise price of the stock options equal to the closing price of our common stock on such date. 25% of these stock options will vest on January 1, 2013 and the remainder will vest ratably on a monthly basis from January 1, 2013 through January 1, 2016, subject to the terms and conditions of the 2012 Equity Incentive Plan, or 2012 Plan. The restricted stock units will vest ratably on a quarterly basis from January 1, 2012 through January 1, 2016, subject to the terms and conditions of the 2012 Plan; provided, however, that all restricted stock units that would have vested in accordance with this schedule prior to the 180th day after the issuance date will first vest on such date.

Director Compensation

The following table sets forth a summary of the compensation we paid to our non-employee directors during 2011.

Name[1]	Fees Earned or Paid in Cash	Option Awards[3]	Total
Paolo Fundaro	$ 40,000	$ 46,800	$ 86,800
Barry Greene[2][4]	30,000	46,800	76,800
Kenneth Noonan, Ph.D.[4]	40,000	46,800	86,800
Robert Roche[2]	10,000	0	10,000
Paul Sekhri[4]	40,000	52,650	92,650
Lorenzo Tallarigo, M.D.	75,000	58,500	133,500
Nicole Williams	40,000	64,350	104,350

(1) Mark Pruzanski has been omitted from this table because he received no compensation for serving on our board of directors. Dr. Pruzanski s compensation as President and Chief Executive Officer for 2011 is detailed in Summary Compensation Table above.

(2) Mr. Greene joined our board on February 8, 2011. Mr. Roche resigned from the board as of February 8, 2011.

(3) Amounts reflect the grant date fair value of option awards granted in 2011 in accordance with ASC Topic 718. For information regarding assumptions underlying the valuation of equity awards, see note 10 to our consolidated financial statements and the discussion under Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Estimates Valuation of Stock-Based Compensation and Warrant Liability Stock-Based Compensation included elsewhere in this prospectus. These amounts do not correspond to the actual value that will be recognized by the directors.

(4) Messrs. Greene, Noonan and Sekhri resigned from the board as of August 9, 2012. Two of the vacancies created by their resignations were filled by Jonathan Silverstein and Klaus Veitinger.

On July 31, 2012, we granted options to purchase an aggregate of 23,794 shares of our common stock at an exercise price of $9.31 per share to our non-employee directors as of January 1, 2012 for service during fiscal year 2012. Ms.

Williams, our audit committee chairperson, received options to purchase 4,759 shares of common stock, of which options to purchase 1,382 shares were immediately vested. Dr. Tallarigo, the chairman of the board, and Mr. Sekhri, the former chairperson of our compensation committee, each received options to purchase 4,326 shares of common stock, of which options to purchase 1,256 shares were immediately vested. Messrs. Fundaro, Greene and Noonan each received options to purchase 3,461 shares of common stock, of which options to purchase 1,005 shares were immediately vested. Pursuant to the terms of

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the 2003 Stock Incentive Plan, as amended, or 2003 Plan, the options granted to Messrs. Greene, Noonan and Sekhri ceased vesting upon their resignation from the board on August 9, 2012 and all vested options prior to their resignation date may be exercised for five years from such date. Under the 2003 Plan, the unvested options for the continuing non-employee directors, other than Dr. Tallarigo as described below, will vest monthly through December 31, 2013, subject to the terms of the 2003 Plan.

On September 13, 2012, our board of directors authorized the grant of the following equity awards to our non-employee directors:

Name	Stock Options	Restricted Stock Units
Paolo Fundaro	3,288	2,596
Jonathan Silverstein	11,249	2,596
Lorenzo Tallarigo	4,673	2,942
Klaus Veitinger	12,980	2,596
Nicole Williams	5,538	2,942

These grants will be made on the 31st day after the completion of this offering, or the issuance date, with the exercise price of the stock options equal to the closing price of our common stock on such date. The stock options of all such directors other than Dr. Tallarigo will vest ratably on a monthly basis from August 9, 2012 through August 9, 2014, subject to the terms and conditions of the 2012 Plan. The restricted stock units of all such directors other than Dr. Tallarigo will vest ratably on a quarterly basis from January 1, 2012 through January 1, 2014, subject to the terms and conditions of the 2012 Plan; provided, however, that all restricted stock units that would have vested in accordance with this schedule prior to the 31st day after the issuance date will first vest on such date.

In September 2012, our board of directors also amended the terms of the stock options previously granted to our non-employee directors under the 2003 Plan to provide that all unvested stock options will immediately vest upon the occurrence of a change of control and also to permit our non-employee directors to exercise their stock options for one year following termination of service instead of 90 days as provided in the form of option agreement under the 2003 Plan.

Prior to September 2012, our director compensation policy was to provide our non-employee directors options to purchase 3,461 shares of common stock annually, which vest over various time periods not exceeding two years from the date of grant, with the chairperson of the audit committee receiving additional options to purchase 1,298 shares of common stock annually and our chairman and the chairperson of our compensation committee receiving additional options to purchase 865 shares of common stock annually. In addition, our non-employee, non-chairman directors received $10,000 per quarter, and our chairman received $18,750 per quarter.

In September 2012, we revised our director compensation policy to continue to provide cash compensation of $10,000 per quarter to each non-employee, non-chairman director and $18,750 per quarter to our chairman. However, equity awards will be granted under the 2012 Plan to our non-employee directors from time to time as may be recommended by our compensation committee and approved by our board of directors. After completion of this offering, we may adopt a new director compensation policy and/or amend our existing director compensation policy to provide for annual equity grants for continuing directors as well as initial equity grants for new directors to be issued under our 2012 Plan.

The vesting of all stock options and restricted stock units granted to Dr. Tallarigo under the 2003 Plan and the 2012 Plan has been suspended starting from the date of this prospectus until October 10, 2013, at which time all such stock

options and restricted stock units that would have vested as of such date will vest and all remaining unvested stock options and restricted stock units will continue vesting in accordance with the original terms.

All directors are eligible to receive reimbursement for reasonable out-of-pocket expenses incurred in connection with attendance at meetings of our board of directors, and our non-employee directors are also

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eligible to receive reimbursement, upon approval of the board of directors or a committee thereof, for reasonable out-of-pocket expenses incurred in connection with attendance at various conferences or meetings with our management.

Equity Incentive Plans

Amended and Restated 2003 Stock Incentive Plan

Our 2003 Stock Incentive Plan was initially adopted by our board of directors and approved by our shareholders on October 16, 2003, and was amended and restated by our board of directors in December 2004, May 2006, June 2008, January 2010 and August 2012. We refer to this plan, as amended, as the 2003 Plan. The 2003 Plan permits us to make grants of non-statutory stock options, incentive stock options, restricted stock awards and other stock-based awards.

Our employees, officers, directors, consultants and advisors are eligible to receive awards under the 2003 Plan; however, incentive stock options may only be granted to our employees. A maximum of 1,889,056 shares of common stock are authorized for issuance under the 2003 Plan, subject to adjustment due to the effect of any stock split, stock dividend, combination, recapitalization or similar transaction.

The 2003 Plan is administered by either the board of directors or one or more committees or subcommittees of our board of directors, which in either case, we refer to as the administrator. In addition, to the extent permitted by applicable law, the board of directors may delegate the authority to grant awards to one or more of our executive officers; provided that board of directors shall fix the terms of the awards granted by such executive officer and the maximum number of shares subject to awards that such executive officer may grant. The 2003 Plan provides that the administrator has the authority to determine:

which employees, officers, directors, consultants and advisors shall be granted options and other awards;
the number of shares of our common stock subject to options and other awards;
the exercise price of each option;
the schedule upon which options become exercisable;
the termination or cancellation provisions applicable to options;
the terms and conditions of other awards, including conditions for repurchase, termination or cancellation, issue price and repurchase price; and
all other terms and conditions upon which each award may be granted in accordance with our plan.

Unless otherwise determined by the administrator or provided for in an award, the 2003 Plan does not permit the transfer of awards except in the event of death and only the recipient may exercise an award during the recipient s lifetime. Shares of common stock acquired upon exercise of a stock option and any gain realized upon exercise of any stock option may be subject to repurchase by, or forfeiture to, us at the discretion of our board of directors if the applicable award agreement provides for the repurchase.

Except as otherwise provided by the administrator and evidenced in a particular award, in the event of a merger or other reorganization event as described under the 2003 Plan, the administrator, in its sole discretion, may take any of the following actions as to some or all of outstanding awards other than restricted stock awards:

provide that all outstanding awards will be assumed or substituted by the successor corporation;
upon written notice to a participant, provide that the participant s options or awards will terminate immediately prior to the consummation of such transaction unless exercised by the participant within a specified period;

provide that all outstanding awards will become exercisable, realizable, deliverable, or restrictions applicable to an award shall lapse, in whole or in part, prior to or upon the occurrence of such reorganization event;

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in the event of a reorganization event pursuant to which our common stockholders will receive a cash payment for each share surrendered in the reorganization event, make or provide a cash payment to the participants equal to the excess, if any, of the acquisition price multiplied by the number of shares of common stock subject to the participant s awards over the aggregate exercise price of all such outstanding awards and any applicable tax withholdings (to the extent the exercise price does not exceed the acquisition price), in exchange for the termination of such awards; and any combination of the actions above.

Except as otherwise evidenced in a particular award agreement or other agreement between a participant and us, in the event of a change in control event, as described in the 2003 Plan, the vesting schedule of an option award or restricted stock award shall be accelerated in part so that one-half of the number of shares that would otherwise have first become vested or free from conditions or restrictions after the date of the change in control event shall immediately become vested or free from conditions or restrictions. The remaining one-half of such number of shares may vest or continue to become free from conditions or restrictions in accordance with the original schedule in the option or restricted stock award agreement; provided, however, that all such options or restricted stock awards will be immediately vested if, on or prior to the first anniversary of the date of the consummation of a change of control, the participant s employment with us or the acquiring or succeeding corporation is terminated for good reason by the participant or is terminated without cause by us or the acquiring or succeeding corporation.

Our board of directors may amend, suspend or terminate the 2003 Plan in any respect at any time, subject to stockholder approval where such approval is required by applicable law or stock exchange rules. The administrator may also amend, modify or terminate any outstanding award, provided that no amendment to an award may materially impair any of the rights of a participant under any awards previously granted without his or her written consent. In September 2012, our board of directors amended the terms of the stock options previously granted to our non-employee directors under the 2003 Plan to provide that all unvested stock options will immediately vest upon the occurrence of a change of control and also to permit our non-employee directors to exercise their stock options for one year following termination of service instead of 90 days as provided in the form of option agreement under the 2003 Plan. In October 2012, our board of directors amended the terms of the stock options granted to Dr. Tallarigo under the 2003 Plan to suspend the vesting of such options until October 10, 2013, as described in Director Compensation above.

As of August 31, 2012, 14,781 shares have been issued upon the exercise of options and the grant of stock awards under the 2003 Plan, 1,333,158 shares are subject to outstanding options under the 2003 Plan and 555,843 shares were available for future grant under the 2003 Plan. Unless earlier terminated by our board of directors, the 2003 Plan will expire on October 16, 2013. Our board of directors has decided not to grant any further awards under the 2003 Plan commencing on the date on which we adopted our 2012 Stock Incentive Plan upon the pricing of this offering. All outstanding stock options granted under the 2003 Plan as of the date of termination will remain outstanding and subject to their respective terms and the terms of the 2003 Plan. The shares available under the 2003 Plan at the time of the adoption of the 2012 Stock Incentive Plan were reserved for the issuance of awards under the 2012 Stock Incentive Plan. Generally, shares that are forfeited or canceled from awards under the 2003 Plan will also be available for future awards under the 2012 Stock Incentive Plan.

2012 Stock Incentive Plan

In September 2012, our board of directors and stockholders approved the 2012 Stock Incentive Plan, which we refer to as the 2012 Plan, which became effective upon the pricing of this offering. The 2012 Plan will expire on September 13, 2022. Under our 2012 Plan, we may grant incentive stock options, non-qualified stock options, restricted and unrestricted stock awards and other stock-based awards. There are 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).

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In addition, the 2012 Plan contains an evergreen provision, which allows for an annual increase in the number of shares of our common stock available for issuance under the plan on the first day of each fiscal year beginning in fiscal year 2013. The annual increase in the number of shares shall be equal to the lowest of:

1,211,533 shares of our common stock;
4% of the number of shares of our common stock outstanding as of such date; and
an amount determined by our board of directors or compensation committee.

The board of directors has authorized our compensation committee to administer the 2012 Plan. In accordance with the provisions of the plan, the compensation committee will determine the terms of options and other awards. The compensation committee or the independent members of our board of directors will determine:

which employees, directors and consultants shall be granted options and other awards;
the number of shares of our common stock subject to options and other awards;
the exercise price of each option, which generally shall not be less than fair market value on the date of grant;
the schedule upon which options become exercisable;
the termination or cancellation provisions applicable to options;
the terms and conditions of other awards, including conditions for repurchase, termination or cancellation, issue price and repurchase price; and
all other terms and conditions upon which each award may be granted in accordance with the 2012 plan.

No participant may receive awards for more than 865,381 shares of our common stock in any fiscal year.

In addition, the administrator may, with the consent of the affected plan participants, reprice or otherwise amend outstanding awards consistent with the terms of the 2012 Plan.

Upon a merger, consolidation or sale of all or substantially all of our assets, the administrator, or the board of directors of any corporation assuming our obligations, may, in its sole discretion, take any one or more of the following actions pursuant to our plan, as to some or all outstanding awards:

provide that outstanding options will be substituted for shares of the successor corporation or consideration payable with respect to our outstanding stock in connection with the corporate transaction;
provide that the outstanding options must be exercised within a certain number of days, either to the extent the options are then exercisable, or at our board of directors discretion, any such options being made partially or fully exercisable;
terminate outstanding options in exchange for payment of an amount equal to the difference between (a) the consideration payable upon consummation of the corporate transaction to a holder of the number of shares into which such option would have been exercisable to the extent then exercisable (or, in our board of directors discretion, any such options being made partially or fully exercisable) and (b) the aggregate exercise price of those options;
provide that outstanding stock grants will be substituted for shares of the successor corporation or consideration payable with respect to our outstanding stock in connection with the corporate transaction;
the terms and conditions of other awards, including conditions for repurchase, termination or cancellation, issue price and repurchase price; and

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terminate outstanding stock grants in exchange for payment of any amount equal to the consideration payable upon consummation of the corporate transaction to a holder of the same number of shares comprising the stock grant, to the extent the stock grant is no longer subject to any forfeiture or repurchase rights (or, at our board of directors discretion, all forfeiture and repurchase rights being waived upon the corporate transaction).

Options granted to our non-employee directors under our 2012 Plan will generally vest ratably on a monthly basis over two years and will generally be exercisable for one year following termination of service. Our forms of equity award agreements for our non-employee directors provide that all unvested equity awards will vest immediately prior to the occurrence of a change of control. In October 2012, our board of directors amended the terms of the stock options and restricted stock units granted to Dr. Tallarigo under the 2012 Plan to suspend the vesting of such options and restricted stock units until October 10, 2013, as described in Director Compensation above.

Options granted to our employees and consultants under our 2012 Plan will generally vest over a four year period, with 25% of the options vesting on the first anniversary of the grant date and the remaining options vesting ratably on a monthly basis during the remaining three years, and will generally be exercisable for three months following termination of service. Our forms of equity award agreements for our employees and consultants provide that in the event of (i) a change of control and the employee s or consultant s service with our company, the acquiring or succeeding corporation or any affiliate of our company or such corporation is terminated by such entity for any reason other than for cause within 12 months of the change of control, then, upon such termination, all of the shares subject to the equity awards which are then unvested will be deemed vested and exercisable as of such termination, or (ii) a change of control in which the acquiring entity does not assume the equity award, then, immediately prior to the change of control, all of the shares subject to the equity awards that are then unvested will be deemed vested and exercisable immediately prior to the change of control.

On the 31st day after the completion of this offering, we will grant to our employees and directors (i) options to purchase 207,505 shares of our common stock with an exercise price equal to the closing price of our common stock as reported by the NASDAQ Stock Market on such date and (ii) restricted stock units for 173,592 shares of our common stock, in each case, under our 2012 Plan.

401(k) Plan and Other Benefits

We have a defined contribution retirement plan, which we refer to as the 401(k) Plan, in which all employees are eligible to participate. Our plan is intended to qualify under Section 401(k) of the Internal Revenue Code so that contributions by employees and by us to the 401(k) Plan and income earned on plan contributions are not taxable to employees until withdrawn or distributed from the 401(k) Plan, and so that contributions, including employee salary deferral contributions, will be deductible by us when made. We do not currently provide matching contributions under the 401(k) Plan but may choose to do so in the future. We also contribute to medical, disability and other standard insurance for our employees.

Rule 10b5-1 Sales Plans

Our directors and executive officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis. Under a Rule 10b5-1 plan and subject to the lock-up agreements described under Underwriting, a broker executes trades pursuant to parameters established by the director or officer when entering into the plan, without further direction from them. The director or officer may amend or terminate the plan in some circumstances. Our directors and executive officers may also buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material, nonpublic information.

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CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

In addition to the director and executive officer compensation arrangements discussed above in Executive and Director Compensation, since January 1, 2009, we have engaged in the following transactions in which the amount involved exceeded $120,000 and in which any director, executive officer or holder of more than 5% of our voting securities, whom we refer to as our principal stockholders, or our director nominee, or affiliates or immediate family members of our directors, director nominee, executive officers and principal stockholders had or will have a material interest. We believe that all of these transactions were on terms as favorable as could have been obtained from unrelated third parties.

Some of our directors are affiliated with our principal stockholders as indicated in the table below:

Director	Affiliation with Principal Stockholder
Lorenzo Tallarigo, M.D	Dr. Tallarigo is the chief executive officer of Genextra S.p.A., which is one of our principal stockholders.
Paolo Fundaro	Mr. Fundaro is the chief financial officer of Genextra S.p.A., which is one of our principal stockholders.
Jonathan Silverstein	Mr. Silverstein is a member of OrbiMed Advisors LLC, whose affiliated fund is one of our principal stockholders.

Private Placements of Securities

In January 2010, we sold to Genextra S.p.A. 13,888,889 shares of our Series B preferred stock and a warrant to purchase 865,381 shares of our common stock at an exercise price of $10.40 per share with a five year term for net proceeds of $24.9 million. Previously, in 2008, we sold 13,888,889 shares of our Series A preferred stock to Genextra S.p.A. for net proceeds of approximately $24.3 million.

Both the Series A and Series B preferred stock accrue dividends at an annual rate of $0.108 per share. The dividends are only payable upon the occurrence of certain events in accordance with the terms of our restated certificate of incorporation but are not payable in connection with conversion of the preferred stock into shares of common stock. All outstanding shares of Series A and Series B preferred stock will be converted into an aggregate of 4,807,674 shares of our common stock upon the completion of this offering.

On August 9, 2012, we entered into a securities purchase agreement with an affiliated fund of OrbiMed Advisors LLC, or OrbiMed, and Genextra S.p.A., or Genextra, pursuant to which we agreed to issue up to an aggregate of 25,000,000 shares of our Series C preferred stock at a price of $2.00 per share for gross proceeds of up to $50.0 million. The securities purchase agreement provides that the Series C preferred stock may be issued in two tranches consisting of 15,000,000 and 10,000,000 shares. The first tranche of Series C preferred stock was issued on August 9, 2012, and resulted in $29.8 million of net proceeds to us. The closing of the second tranche of Series C preferred stock will only occur if we do not complete an initial public offering of our common stock on or prior to the one year anniversary of the closing of the first tranche.

The Series C preferred stock accrue dividends at an annual rate of $0.12 per share. The dividends are only payable upon the occurrence of certain events in accordance with the terms of our restated certificate of incorporation but are not payable in connection with the conversion of the Series C preferred stock. All of our outstanding shares of Series

C preferred stock will convert into 2,596,143 shares of our common stock upon the completion of this offering.

The investors have been granted certain demand and piggyback registration rights in respect of their securities under our third amended and restated stockholders agreement. Under the securities purchase agreement, we have agreed to indemnify each purchaser of our Series C preferred stock and its employees, agents, stockholders and affiliates, up to an aggregate amount equal to the purchase price of the Series C preferred stock until August 9, 2015, for any and all losses, judgments or damages sustained or incurred by or asserted against such indemnified party arising out of or in any way relating to any material breach of our representations and warranties, the failure by us to fulfill any material obligation, agreement or covenant under

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the securities purchase agreement or the third amended and restated stockholders agreement, or any cost or expense, including reasonable legal fees incurred in connection with enforcing the rights of such indemnified party.

See Principal Stockholders for more information about shares held by these entities.

Reimbursement of Expenses

In connection with the Series B preferred stock financing in January 2010, we reimbursed Genextra approximately $50,000 for expenses incurred during the course of the transaction.

In connection with the Series C preferred stock financing in August 2012, we agreed to reimburse Genextra and OrbiMed up to $50,000 and $150,000, respectively, for expenses incurred by such stockholders in connection with the transaction.

Agreements with Stockholders

In connection with the Series B preferred stock financing, we entered into the Second Amended and Restated Stockholders Agreement, dated as of January 20, 2010, with certain of our stockholders, including our principal stockholders and their affiliates. Subsequently, on August 9, 2012, we entered into the Third Amended and Restated Stockholders Agreement with certain of our stockholders, including our principal stockholders and their affiliates, in connection with the Series C preferred stock financing. All of the provisions of this agreement will terminate immediately upon completion of the offering, other than the provisions relating to registration rights, which will continue in effect following completion of the offering and entitle the holders of such rights to have us register their shares of our common stock for sale in the United States. See Description of Capital Stock Registration Rights.

Director and Executive Officer Compensation

Please see Executive and Director Compensation for information regarding compensation of directors and executive officers.

Employment Agreements

We have entered into employment agreements with our executive officers. For more information regarding our agreements with our named executive officers for the fiscal year ended 2011, see Executive and Director Compensation Narrative to Summary Compensation Table Employment Arrangements with Our Named Executive Officers.

Indemnification Agreements

We have entered into or plan to enter into indemnification agreements with each of our directors and officers and our director nominee the form of which is attached as an exhibit to the registration statement of which this prospectus is a part. The indemnification agreements and our restated certificate of incorporation and restated by-laws require us to indemnify our directors and officers to the fullest extent permitted by Delaware law. See Management Limitation of Directors and Officers Liability and Indemnification.

Participation in this Offering

An affiliate of OrbiMed Advisors LLC, which holds more than 5% of our common stock, has agreed to purchase an aggregate of $5.0 million in shares of our common stock in this offering at the initial public offering price. In addition, New Leaf Venture Partners, L.L.C., of which Dr. Akkaraju, our director nominee, is a managing director, and its affiliated funds have agreed to purchase an aggregate of $10.5 million in shares of our common stock in this offering at the initial public offering price. Any shares purchased by these entities will be subject to lock-up restrictions described in Shares Eligible for Future Sale.

Policy for Approval of Related Person Transactions

Pursuant to the written charter of our audit committee that will be in effect upon completion of this offering, the audit committee is responsible for reviewing and approving, prior to our entry into any such transaction, all transactions in which we are a participant and in which any parties related to us, including our executive officers,

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our directors, beneficial owners of more than 5% of our securities, immediate family members of the foregoing persons and any other persons whom our board of directors determines may be considered related parties under Item 404 of Regulation S-K, has or will have a direct or indirect material interest.

In reviewing and approving such transactions, the audit committee shall obtain, or shall direct our management to obtain on its behalf, all information that the committee believes to be relevant and important to a review of the transaction prior to its approval. Following receipt of the necessary information, a discussion shall be held of the relevant factors if deemed to be necessary by the committee prior to approval. If a discussion is not deemed to be necessary, approval may be given by written consent of the committee. This approval authority may also be delegated to the chair of the audit committee in some circumstances. No related party transaction shall be entered into prior to the completion of these procedures.

The audit committee or its chair, as the case may be, shall approve only those related party transactions that are determined to be in, or not inconsistent with, the best interests of us and our stockholders, taking into account all available facts and circumstances as the committee or the chair determines in good faith to be necessary in accordance with principles of Delaware law generally applicable to directors of a Delaware corporation. These facts and circumstances will typically include, but not be limited to, the benefits of the transaction to us; the impact on a director s independence in the event the related party is a director, an immediate family member of a director or an entity in which a director is a partner, stockholder or executive officer; the availability of other sources for comparable products or services; the terms of the transaction; and the terms of comparable transactions that would be available to unrelated third parties or to employees generally. No member of the audit committee shall participate in any review, consideration or approval of any related party transaction with respect to which the member or any of his or her immediate family members has an interest.

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PRINCIPAL STOCKHOLDERS

The following table sets forth certain information regarding the beneficial ownership of our common stock as of September 26, 2012, on a pre-offering basis and as adjusted to reflect the sale of our common stock offered by this prospectus, by:

- our named executive officers;
- each of our directors and our director nominee;
- all of our current directors and executive officers and our director nominee as a group; and
- each stockholder known by us to own beneficially more than five percent of our common stock.

Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission and includes voting or investment power with respect to the securities. Shares of common stock that may be acquired by an individual or group within 60 days of September 26, 2012, pursuant to the exercise of options or warrants, are deemed to be outstanding for the purpose of computing the percentage ownership of such individual or group, but are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person shown in the table. Percentage of ownership before this offering is based on an aggregate of 10,733,483 shares, consisting of (i) 3,329,666 shares of common stock outstanding on September 26, 2012 and (ii) 7,403,817 shares of common stock into which all of our preferred stock outstanding as of September 26, 2012 will be converted upon the completion of this offering.

An affiliate of OrbiMed Advisors LLC, which holds more than 5% of our common stock, has agreed to purchase an aggregate of $5.0 million in shares of our common stock in this offering at the initial public offering price. New Leaf Venture Partners, L.L.C., of which Dr. Akkaraju, our director nominee, is a managing director, and its affiliated funds have agreed to purchase an aggregate of $10.5 million in shares of our common stock in this offering at the initial public offering price. The following table reflects the purchase of these shares in this offering by these investors or their affiliated entities.

Except as indicated in footnotes to this table, we believe that the stockholders named in this table have sole voting and investment power with respect to all shares of common stock shown to be beneficially owned by them, based on information provided to us by such stockholders. Unless otherwise indicated, the address for each director and executive officer and our director nominee is: c/o Intercept Pharmaceuticals, Inc., 18 Desbrosses Street, New York, NY 10013.

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Beneficial Owner	Number of Shares of Common Stock Beneficially Owned		Percentage of Common Stock Beneficially Owned	
	Before Offering	After Offering	Before Offering	After Offering
Directors, Director Nominee and Executive Officers				
Mark Pruzanski, M.D.(1)	785,069	785,069	7.0 %	4.9 %
David Shapiro, M.D.(2)	140,668	140,668	1.3 %	*
Barbara Duncan(3)	113,777	113,777	1.0 %	*
Lorenzo Tallarigo, M.D.(4)	8,072,530	8,072,530	69.5%	48.6 %
Paolo Fundaro(5)	18,021	18,021	*	*
Jonathan Silverstein(6)	1,817,300	2,150,634	16.9%	13.7 %
Klaus Veitinger, M.D				
Nicole Williams(7)	22,185	22,185	*	*
Srinivas Akkaraju, M.D., Ph.D.(8)		700,000		4.5 %
All current executive officers and directors and director nominee as a group (10 persons)(9)	11,006,532	12,039,866	89.1%	69.4 %
Five Percent Stockholders				
Genextra S.p.A.(10)	8,052,598	8,052,598	69.4%	48.5 %
OrbiMed Private Investments IV, LP(11)	1,817,300	2,150,634	16.9%	13.7 %

* Represents beneficial ownership of less than 1% of the shares of common stock.

(1) Consists of 380,767 shares of common stock and options to purchase 404,302 shares of common stock that are exercisable within 60 days of September 26, 2012.

(2) Consists of options to purchase 140,668 shares of common stock that are exercisable within 60 days of September 26, 2012.

(3) Consists of options to purchase 113,777 shares of common stock that are exercisable within 60 days of September 26, 2012.

(4) Consists of (a) 1,600,700 shares of common stock owned by Genextra S.p.A., 5,586,517 shares of common stock into which the shares of preferred stock held by Genextra S.p.A. are convertible, and 865,381 shares underlying warrants held by Genextra S.p.A., and (b) options to purchase 19,932 shares of common stock which are exercisable within 60 days of September 26, 2012 that are held directly by Dr. Tallarigo. Dr. Tallarigo is the chief executive officer of Genextra S.p.A. and, in such capacity, Dr. Tallarigo exercises voting control over the shares of common stock owned by Genextra S.p.A. and investment control over such shares as authorized by the board of directors of Genextra S.p.A. Dr. Tallarigo disclaims beneficial ownership with respect to any such shares, except to the extent of his pecuniary interest therein, if any.

(5) Consists of options to purchase 18,021 shares of common stock which are exercisable within 60 days of September 26, 2012.

(6) Consists of the shares described in note (11) below. Mr. Silverstein disclaims beneficial ownership of the shares described in note (11), except to the extent of his pecuniary interest therein, if any.

(7) Consists of options to purchase 22,185 shares of common stock which are exercisable within 60 days of September 26, 2012.

(8) The number of shares beneficially owned after the offering consists of 700,000 shares to be purchased by New Leaf Ventures II, L.P. in this offering. Srinivas Akkaraju, our director nominee, Philippe O. Chambon, Jeani Delagardelle, Ronald M. Hunt, Vijay K. Lathi, and James Niedel, the members of the Investment Committee of New Leaf Venture Management II, L.L.C., which is the general partner of New Leaf Venture Associates II, L.P.,

which in turn is the general partner of New Leaf Ventures II, L.P., have the power to vote or dispose of these shares and therefore each of the foregoing members of the investment committee may be deemed to have voting and investment power with respect to such shares. Each of the foregoing members of the Investment Committee disclaims beneficial ownership of such shares except to the extent of their pecuniary interest therein, if any.

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(9) Number of shares beneficially owned before the offering consists of (a) 1,981,467 shares of common stock beneficially owned by our officers and directors, (b) 5,586,517 shares of common stock into which the shares of preferred stock beneficially owned by Dr. Tallarigo are convertible, (c) 1,817,300 shares of common stock into which the shares of preferred stock beneficially owned by Mr. Silverstein are convertible, (d) 865,381 shares of common stock underlying the warrants beneficially owned by Dr. Tallarigo, and (e) options to purchase 755,867 shares of common stock beneficially owned by our officers and directors which are exercisable within 60 days of September 26, 2012. The number of shares beneficially owned after the offering includes the aforementioned shares and (A) 700,000 shares to be purchased by New Leaf Ventures II, L.P. in this offering, and (B) 333,334 shares to be purchased by OrbiMed Private Investments IV, LP in this offering. See notes (1) through (8) above.

(10) Consists of (a) 1,600,700 shares of common stock owned by Genextra S.p.A., (b) 5,586,517 shares of common stock into which the shares of preferred stock held by Genextra S.p.A. are convertible, and (c) 865,381 shares underlying warrants held by Genextra S.p.A. Dr. Tallarigo is the chief executive officer of Genextra S.p.A. and, in such capacity, Dr. Tallarigo exercises voting control over the shares of common stock owned by Genextra S.p.A. and investment control over such shares as authorized by the board of directors of Genextra S.p.A. Dr. Tallarigo disclaims beneficial ownership with respect to any such shares, except to the extent of his pecuniary interest therein, if any. The address of each of Genextra S.p.A. and its affiliates is Via G. De Grassi, 11, 20123 Milan, Italy.

(11) Number of shares beneficially owned before the offering consists of 1,817,300 shares of common stock into which the shares of preferred stock beneficially owned by OrbiMed Private Investments IV, LP are convertible. The number of shares beneficially owned after the offering includes the aforementioned shares and 333,334 shares to be purchased by OrbiMed Private Investments IV, LP in this offering. OrbiMed Capital GP IV LLC is the general partner of OrbiMed Private Investments IV, LP and OrbiMed Advisors LLC is the managing member of OrbiMed Capital GP IV LLC. Samuel D. Isaly is the managing member of and owner of a controlling interest in OrbiMed Advisors LLC and may be deemed to have voting and investment power over the shares held by OrbiMed Private Investments IV, LP noted above. Each of OrbiMed Capital GP IV LLC, OrbiMed Advisors LLC and Mr. Isaly disclaims beneficial ownership of such shares, except to the extent of its or his pecuniary interest therein, if any. Mr. Silverstein, a member of our board of directors, is a member of OrbiMed Advisors LLC. The address for OrbiMed Private Investments IV, LP is c/o OrbiMed Advisors LLC, 601 Lexington Avenue, 54th Floor, New York, NY 10022.

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DESCRIPTION OF CAPITAL STOCK

The following is a summary of our capital stock and provisions of our restated certificate of incorporation and restated by-laws, as they will be in effect upon the closing of this offering. For more detailed information, please see our restated certificate of incorporation and restated by-laws, which are filed with the Securities and Exchange Commission as exhibits to the registration statement of which this prospectus forms a part. The descriptions of our common stock and preferred stock reflect changes to our capital structure that will occur upon the closing of this offering.

Upon completion of this offering, we will be 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, and there will be 15,733,483 shares of common stock and no shares of preferred stock outstanding. Assuming the conversion of all of our preferred stock, as of August 31, 2012, we would have had outstanding an aggregate of 10,733,483 shares of common stock, consisting of (i) 3,329,666 shares of common stock outstanding on such date and (ii) 7,403,817 shares of common stock into which all of our preferred stock outstanding as of such date would have been converted, which were held of record by 98 stockholders. In addition, as of August 31, 2012, there were outstanding options to purchase 1,333,158 shares of common stock and outstanding warrants to purchase 1,232,767 shares of common stock.

Common Stock

Holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders, and do not have cumulative voting rights. Subject to preferences that may be applicable to any outstanding shares of preferred stock, holders of common stock are entitled to receive ratably such dividends, if any, as may be declared from time to time by our board of directors out of funds legally available for dividend payments. All outstanding shares of common stock are fully paid and nonassessable, and the shares of common stock to be issued upon completion of this offering will be fully paid and nonassessable. The holders of common stock have no preferences or rights of conversion, exchange, pre-emptive or other subscription rights. There are no redemption or sinking fund provisions applicable to the common stock. In the event of any liquidation, dissolution or winding-up of our affairs, holders of common stock will be entitled to share ratably in any of our assets remaining after payment or provision for payment of all of our debts and obligations and after liquidation payments to holders of outstanding shares of preferred stock, if any.

Preferred Stock

Our preferred stock, if issued, would have priority over our common stock with respect to dividends and other distributions, including the distribution of assets upon liquidation. Our board of directors has the authority, without further stockholder authorization, to issue from time to time shares of preferred stock in one or more series and to fix the terms, limitations, relative rights and preferences and variations of each series. Although we have no present plans to issue any shares of preferred stock, the issuance of shares of preferred stock, or the issuance of rights to purchase such shares, could decrease the amount of earnings and assets available for distribution to the holders of common stock, could adversely affect the rights and powers, including voting rights, of the common stock, and could have the effect of delaying, deterring or preventing a change of control of us or an unsolicited acquisition proposal.

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Warrants

As of August 31, 2012, we had warrants outstanding to purchase the number of shares of our common stock at the exercise prices and expiration dates set forth below. Warrants entitle the holder to purchase shares of our common stock, as applicable, at the specified exercise price at any time prior to the expiration date.

	Warrants to Purchase Common Stock	Weighted Average Exercise Price	Expiration
Warrants issued in 2003[1][2][3]	2,163	$ 2.89	October 24, 2013
Warrants issued in 2003[1][2]	2,163	8.67	October 24, 2013
Warrants issued in 2004[1][2][3]	117,642	2.89	October 27, 2013
Warrants issued in 2004[1][2][3]	19,609	2.89	May 4, 2014
Warrants issued in 2004[1][2]	117,640	8.67	October 27, 2013
Warrants issued in 2008[1][4][5]	108,169	10.40	May 23, 2013
Warrants issued in 2010[1][4][6]	865,381	10.40	January 25, 2015
Total	1,232,767	$ 9.38	

(1) Each of these warrants has a net exercise provision under which the holder may, in lieu of payment of the exercise price in cash, surrender the warrant and receive a net amount of shares of our common stock based on the fair market value of the underlying shares of our common stock at the time of exercise of the warrant, after deduction of the aggregate exercise price. Each warrant also contains provisions for the adjustment of the exercise price and the number of shares issuable upon the exercise of the warrant in the event of certain stock dividends, stock splits, reorganizations, reclassifications and consolidations.

(2) Pursuant to the terms of these warrants, we have agreed to file a registration statement registering the shares underlying these warrants within 90 days after the completion of this offering unless such shares are eligible for sale under Rule 144.

(3) Each of these warrants contains anti-dilution provisions providing for adjustments to the exercise price upon the issuance of shares of our common stock for no consideration or at a price less than the exercise price pursuant to a merger, asset acquisition or other business combination where a third party acquires a majority equity interest in or all or substantially all of the assets of our company. If such a lower-priced issuance occurs, the exercise price of these warrants will be reduced to the price at which our common stock is issued.

(4) Each of these warrants contains anti-dilution provisions providing for adjustments to the exercise price upon the issuance of shares of our common stock for no consideration or at a price less than the exercise price, excluding certain shares of our common stock issuable upon exercise of options, warrants or conversion of convertible securities. If such a lower-priced issuance occurs, the exercise price of the warrants will be reduced based on a weighted average of the difference between the exercise price of the warrants and the issuance price of the shares.

(5) An aggregate of 41,176 of the shares underlying these warrants are entitled to certain registration rights set forth in our third amended and restated stockholders agreement. See Registration Rights below for a description of these registration rights.

(6) The shares underlying each of this warrant are entitled to certain registration rights set forth in our third amended and restated stockholders agreement. See Registration Rights below for a description of these registration rights.

Registration Rights

On August 9, 2012, we entered into a third amended and restated stockholders agreement with certain holders of our preferred stock, common stock and warrants, which provide such holders with registration rights with respect to certain shares of our common stock, including shares of our common stock into which the shares of our preferred stock are convertible, the shares of our common stock are issuable upon exercise of the warrants. The summary of the registration rights below is qualified by reference to the third amended and restated stockholders agreement, a copy of which is attached as an exhibit to the registration statement of which this prospectus is a part. After this offering, an aggregate of 12,650,912 shares of outstanding common

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stock and shares of common stock underlying our warrants and options will be registrable securities pursuant to the terms of the third amended and restated stockholders agreement.

Our warrants that were issued in 2003 and 2004 contain registration rights in the forms of the warrant, copies of which are filed as an exhibit to the registration statement of which this prospectus is a part. See Warrants above for a description of the registration rights relating to these warrants.

Demand Registration Rights. Commencing on the six-month anniversary of the completion of this offering, the holders of the registrable shares will be entitled to certain demand registration rights. If certain of our major security holders who are parties to the third amended and restated stockholders agreement or holders of at least 30% of the registrable shares then outstanding request a registration of registrable shares having an aggregate value of at least $25.0 million (based on the market price or fair value on the date of such request), we will be required to register their shares. We may be required to effect up to three registrations in accordance with such demand registration rights. Stockholders with these registration rights who are not part of an initial registration demand are entitled to notice and are entitled to include their registrable shares in the registration. Under certain circumstances, our board of directors may suspend our obligations to register registrable shares.

Piggyback Registration Rights. In the event that we propose to register any of our securities under the Securities Act either for our own account or for the account of other stockholders (other than in connection with this offering, a registration statement on Form S-8 or Form S-4 or to cover securities proposed to be issued in exchange for securities or assets of another corporation), the holders of the registrable shares will be entitled to certain piggyback registration rights allowing the holders to include their shares in such registration, subject to certain marketing and other limitations. As a result, whenever we propose to file a registration statement under the Securities Act, the holders of these shares of our common stock are entitled to notice of the registration and have the right, subject to limitations that the underwriters may impose on the number of shares included in the registration, to include their shares in the registration.

Shelf Registration Rights. If we become eligible to file registration statements on Form S-3 that will become automatically effective upon filing, the holders of the registrable shares will be entitled to require us to register all or a portion of their registrable shares on Form S-3 if the registrable shares held by such holders have an aggregate value of at least $5.0 million (based on the public market price on the date of such request). If we become eligible to file use a Form S-3 that becomes automatically effective upon filing, we are required to use our commercially reasonable efforts to file a Form S-3 registration statement as soon as practicable, and in any event within 30 days after the request, except under limited circumstances. There is no limit to the number of registrations that we may be required to make in accordance with such Form S-3 registration rights. Stockholders with these registration rights who are not part of an initial registration demand are entitled to notice and are entitled to include their registrable shares in the registration. Under certain circumstances, our board of directors may suspend our obligations to register registrable shares.

We have agreed to pay certain registration expenses of the holders of the shares registered pursuant to any demand, piggyback and shelf registrations described above.

Anti-Takeover Effects of Delaware Law and Our Restated Certificate of Incorporation and Restated By-Laws

The provisions of Delaware law and our restated certificate of incorporation and restated by-laws to be effective upon completion of this offering could discourage or make it more difficult to accomplish a proxy contest or other change

in our management or the acquisition of control by a holder of a substantial amount of our voting stock. It is possible that these provisions could make it more difficult to accomplish, or could deter, transactions that stockholders may otherwise consider to be in their best interests or in our best interests. These provisions are intended to enhance the likelihood of continuity and stability in the composition of our board of directors and in the policies formulated by the board of directors and to discourage certain types of transactions that may involve an actual or threatened change of our control. These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy fights. Such provisions also may have the effect of preventing changes in our management.

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Delaware Statutory Business Combinations Provision. We are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law. Section 203 prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. For purposes of Section 203, a business combination is defined broadly to include a merger, asset sale or other transaction resulting in a financial benefit to the interested stockholder, and, subject to certain exceptions, an interested stockholder is a person who, together with his or her affiliates and associates, owns, or within three years prior, did own, 15% or more of the corporation s voting stock.

Advance Notice Provisions for Stockholder Proposals and Stockholder Nominations of Directors. Our restated by-laws provide that, for nominations to the board of directors or for other business to be properly brought by a stockholder before a meeting of stockholders, the stockholder must first have given timely notice of the proposal in writing to our Secretary. For an annual meeting, a stockholder s notice generally must be delivered not less than 90 days nor more than 120 days prior to the first anniversary of the previous year s annual meeting date. For a special meeting, the notice must generally be delivered not earlier than the 90th day prior to the meeting and not later than the later of (1) the 60th day prior to the meeting or (2) the 10th day following the day on which public announcement of the meeting is first made. Detailed requirements as to the form of the notice and information required in the notice are specified in the restated by-laws. If it is determined that business was not properly brought before a meeting in accordance with our by-law provisions, such business will not be conducted at the meeting.

Special Meetings of Stockholders. Special meetings of the stockholders may be called only by our board of directors pursuant to a resolution adopted by a majority of the total number of directors.

No Stockholder Action by Written Consent. Any action to be effected by our stockholders must be effected at a duly called annual or special meeting of the stockholders *provided, however,* that if any one stockholder, together with its affiliates, collectively holds a majority of the voting power of the then-outstanding shares of our capital stock, action may be taken without a meeting and vote, through the written consent of holders of the requisite number of votes necessary to authorize or take such action at a meeting.

Super Majority Stockholder Vote Required for Certain Actions. The Delaware General Corporation Law provides generally that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation s certificate of incorporation or by-laws, unless the corporation s certificate of incorporation or by-laws, as the case may be, requires a greater percentage. Our restated certificate of incorporation requires the affirmative vote of the holders of at least 80% of our outstanding voting stock to amend or repeal any of the provisions discussed in this section of this prospectus entitled Anti-Takeover Effects of Delaware Law and Our Restated Certificate of Incorporation and Restated By-Laws. This 80% stockholder vote would be in addition to any separate class vote that might in the future be required pursuant to the terms of any preferred stock that might then be outstanding. A 80% vote is also required for any amendment to, or repeal of, our restated by-laws by the stockholders. Our restated by-laws may be amended or repealed by a simple majority vote of the board of directors.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock will be VStock Transfer, LLC.

Stock Market Listing

Our common stock has been approved for listing on the NASDAQ Global Market under the symbol ICPT.

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SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock, and a liquid public trading market for our common stock may not develop or be sustained after this offering. If a public market does develop, future sales of significant amounts of our common stock, including shares issued upon exercise of outstanding options or warrants, or the anticipation of those sales, could adversely affect the public market prices prevailing from time to time and could impair our ability to raise capital through sales of our equity securities. Our common stock has been approved for listing on the NASDAQ under the symbol ICPT.

Upon the closing of the offering made hereby, we will have outstanding an aggregate of 15,733,483 shares of common stock, assuming no exercise by the underwriters of their option to purchase additional shares and no exercise of outstanding options or warrants. Of these shares, all of the shares of our common stock sold in this offering will be freely tradable without restriction or further registration under the Securities Act, except for any shares of our common stock purchased by our affiliates, as that term is defined in Rule 144 under the Securities Act, whose sales would be subject to the Rule 144 resale restrictions described below. In addition, any shares sold in this offering to entities affiliated with our existing stockholders and directors and entities affiliated with our director nominee will be subject to lock-up agreements.

The remaining shares of common stock will be restricted securities, as that term is defined in Rule 144 under the Securities Act. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under the Securities Act. One such safe-harbor exemption is Rule 144, which is summarized below.

Subject to the lock-up agreements described below and the provisions of Rule 144 under the Securities Act, these restricted securities will be available for sale in the public market as follows:

Date Available for Sale	Shares Eligible for Sale	Comment
Date of prospectus	4,139,295	Shares sold in the offering and shares that may be sold under Rule 144 that are not subject to a lock-up
90 days after date of prospectus*	4,139,295	Shares that are not subject to a lock-up and can be sold under Rule 144
180 days** after date of prospectus*	15,733,483	Lock-up released; shares that can be sold under Rule 144

* Inclusive of the shares in the rows above.

** 180 days corresponds to the lock-up period described below in Lock-up Agreements. This lock-up period may be extended or shortened under certain circumstances as described in Underwriting. However, Merrill Lynch, Pierce, Fenner & Smith Incorporated, as the representative of the underwriters, may in its sole discretion, release all or any portion of the shares from the restrictions in any of these agreements.

Rule 144

Affiliate Resales of Shares

Affiliates of ours must generally comply with Rule 144 if they wish to sell any shares of our common stock in the public market, whether or not those shares are restricted securities. Restricted securities are any securities acquired from us or one of our affiliates in a transaction not involving a public offering. All shares of our common stock issued prior to the closing of the offering made hereby, and the shares of common stock that our preferred stock can be converted into or that are exercisable upon warrants, are considered to be restricted securities. The shares of our common stock sold in this offering are not considered to be restricted securities.

In general, subject to the lock-up agreements described below, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours, or who was an affiliate of ours at any time during the three months immediately before a sale can sell restricted shares of our common stock in compliance with the following requirements of Rule 144.

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Holding period: If the shares are restricted securities, an affiliate must have beneficially owned the shares of our common stock for at least six months.

Manner of sale: An affiliate must sell its shares in broker s transactions or certain riskless principal transactions or to market makers, each within the meaning of Rule 144.

Limitation on number of shares sold: An affiliate is only allowed to sell within any three-month period an aggregate number of shares of our common stock that does not exceed the greater of:

one percent of the number of the total number of shares of our common stock then outstanding, which will equal approximately 157,000 shares immediately after this offering; and
the average weekly trading volume in our common stock on the stock exchange where our common stock is traded during the four calendar weeks preceding either (i) to the extent that the seller is required to file a notice on Form 144 with respect to such sale, the date of filing such notice, (ii) the date of receipt of the order to execute the transaction by the broker or (iii) the date of execution of the transaction with the market maker.

Current public information: An affiliate may only resell its restricted securities to the extent that adequate current public information, as defined in Rule 144, is available about us, which, in our case, means that we have been subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act for a period of at least 90 days prior to the date of the sale and we have filed all reports with the Securities and Exchange Commission required by those sections during the preceding 12 months (or such shorter period that we have been subject to these filing requirements).

Notice on Form 144: If the number of shares of our common stock being sold by an affiliate under Rule 144 during any three-month period exceeds 5,000 shares or has an aggregate sale price in excess of $50,000, then the seller must file a notice on Form 144 with the Securities and Exchange Commission and the stock exchange on which our common stock is traded concurrently with either the placing of a sale order with the broker or the execution directly with a market maker.

Non-Affiliate Resales of Restricted Shares

Any person or entity who is not an affiliate of ours and who has not been an affiliate of ours at any time during the three months preceding a sale is only required to comply with Rule 144 in connection with sales of restricted shares of our common stock. Subject to the lock-up agreements described below, those persons may sell shares of our common stock that they have beneficially owned for at least one year without any restrictions under Rule 144 immediately following the effective date of the registration statement of which this prospectus is a part.

Further, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is not an affiliate of ours at the time such person sells shares of our common stock, and has not been an affiliate of ours at any time during the three months preceding such sale, and who has beneficially owned such shares of our common stock, as applicable, for at least six months but less than a year, is entitled to sell such shares so long as there is adequate current public information, as defined in Rule 144, available about us.

Resales of restricted shares of our common stock by non-affiliates are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144, described above.

Rule 701

In general, under Rule 701 of the Securities Act, any of our employees, directors, officers, consultants or advisors who purchases shares from us in connection with a compensatory stock or option plan or other written agreement before the effective date of this offering is entitled to resell such shares 90 days after the effective date of this offering in reliance on Rule 144, without having to comply with the holding period requirements or other restrictions contained in Rule 701.

The Securities and Exchange Commission has indicated that Rule 701 will apply to typical stock options granted by an issuer before it becomes subject to the reporting requirements of the Securities Exchange Act, along with the shares acquired upon exercise of such options, including exercises after the date of this prospectus. Securities issued in reliance on Rule 701 are restricted securities and, subject to the contractual

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restrictions described above, beginning 90 days after the date of this prospectus, may be sold by persons other than affiliates, as defined in Rule 144, subject only to the manner of sale provisions of Rule 144 and by affiliates under Rule 144 without compliance with its one-year minimum holding period requirement.

Registration Rights

Upon completion of this offering, the holders of approximately 12,650,912 shares of common stock, including shares of common stock issuable upon the exercise of outstanding warrants and options, or their transferees, will be entitled to various rights with respect to the registration of these shares under the Securities Act. Registration of these shares under the Securities Act would result in these shares becoming freely tradable without restriction under the Securities Act immediately upon the effectiveness of the registration, except for shares held by affiliates. See Description of Capital Stock Registration Rights.

Equity Incentive Awards

As of August 31, 2012, options to purchase a total of 1,016,506 shares of common stock were outstanding and exercisable. 986,660 of such shares subject to options are subject to lock-up agreements. As of August 31, 2012, 555,843 shares of our common stock were reserved for future issuance under our 2003 Plan. Our board of directors has decided not to grant any further awards under the 2003 Plan upon the effectiveness of our 2012 Plan, which became effective upon the pricing of this offering. The shares available under the 2003 Plan at the time the 2012 Stock Incentive Plan became effective were reserved for the issuance of awards under the 2012 Plan. Generally, shares that are forfeited or canceled from awards under the 2003 Plan will also be available for future awards under the 2012 Plan. There are 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 and any shares added pursuant to the evergreen provision of the plan).

In addition, on the 31st day after the completion of this offering, we will grant to our employees and directors (i) options to purchase 207,505 shares of our common stock and (ii) restricted stock units for 173,592 shares of our common stock, in each case, under our 2012 Plan. The shares underlying these grants will be subject to the lock-up agreements.

Upon completion of this offering, we intend to file a registration statement on Form S-8 under the Securities Act covering all shares of common stock subject to outstanding options, restricted stock unit awards or issuable pursuant to our stock plans. Subject to Rule 144 volume limitations applicable to affiliates, shares registered under any registration statements will be available for sale in the open market, except to the extent that the shares are subject to vesting restrictions with us or the contractual restrictions described below.

Warrants

As of August 31, 2012, we had outstanding warrants to purchase an aggregate of 1,232,767 shares of our common stock at a weighted-average exercise price of $9.38 per share. Any shares purchased pursuant to these warrants will be restricted shares and may be sold in the public market only if they are registered under the Securities Act or qualify for an exemption from such registration.

Lock-up Agreements

As of September 26, 2012, our officers, directors and substantially all of our other existing security holders, who hold an aggregate of approximately 13,842,266 shares of our common stock and/or shares underlying outstanding options and warrants to purchase common stock, have agreed, subject to limited exceptions, not to offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, or enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock held prior to the offering for a period of 180 days after the date of this prospectus, without the prior written consent of Merrill Lynch, Pierce, Fenner & Smith Incorporated, the representative of the underwriters. Merrill Lynch, Pierce, Fenner & Smith Incorporated, as the representative of the underwriters, may in its sole discretion choose to release any or all of these shares from these restrictions prior to the expiration of the 180-day period.

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MATERIAL U.S. FEDERAL TAX CONSIDERATIONS TO NON-U.S. HOLDERS

The following is a general discussion of material U.S. federal income and estate tax considerations relating to ownership and disposition of our common stock by a non-U.S. holder. For purposes of this discussion, the term non-U.S. holder means a beneficial owner of our common stock that is not, for U.S. federal income tax purposes:

an individual who is a citizen or resident of the United States;
a corporation, or other entity treated as a corporation for U.S. federal income tax purposes, created or organized in or under the laws of the United States or of any political subdivision of the United States;
an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
a trust, if a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust or if the trust has a valid election to be treated as a U.S. person under applicable U.S. Treasury Regulations.

An individual may be treated as a resident instead of a nonresident of the United States in any calendar year for U.S. federal income tax purposes if the individual was present in the United States for at least 31 days in that calendar year and for an aggregate of at least 183 days during the three-year period ending with the current calendar year. For purposes of this calculation, all of the days present in the current year, one-third of the days present in the immediately preceding year and one-sixth of the days present in the second preceding year are counted. Subject to the provisions of certain tax treaties between the U.S. and other nations, non-citizens of the U.S. treated as U.S. residents are taxed for U.S. federal income tax purposes as if they were U.S. citizens.

This discussion is based on current provisions of the Code, existing and proposed U.S. Treasury Regulations promulgated thereunder, current administrative rulings and judicial decisions, all as in effect as of the date of this prospectus and all of which are subject to change or to differing interpretation, possibly with retroactive effect. Any change could alter the tax consequences to non-U.S. holders described in this prospectus. In addition, the Internal Revenue Service, or the IRS, could challenge one or more of the tax consequences described in this prospectus.

We assume in this discussion that each non-U.S. holder holds shares of our common stock as a capital asset (generally, property held for investment). This discussion does not address all aspects of U.S. federal income and estate taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder s individual circumstances nor does it address any aspects of state, local or non-U.S. taxes, or U.S. federal taxes other than income and estate taxes. This discussion also does not consider any specific facts or circumstances that may apply to a non-U.S. holder and does not address the special tax rules applicable to particular non-U.S. holders, such as:

insurance companies;
tax-exempt organizations;
financial institutions;
brokers or dealers in securities;
regulated investment companies;
pension plans;
controlled foreign corporations;
passive foreign investment companies;
owners that hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment;
certain U.S. expatriates;

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persons subject to the alternative minimum tax; or
persons that acquire our common stock as compensation for services.

In addition, this discussion does not address the tax treatment of partnerships or persons who hold their common stock through partnerships or other entities that are transparent for U.S. federal income tax purposes. A partner in a partnership or other transparent entity that will hold our common stock should consult his, her or its own tax advisor regarding the tax consequences of the ownership and disposition of our common stock through a partnership or other transparent entity, as applicable.

Prospective investors should consult their own tax advisors regarding the U.S. federal, state, local and non-U.S. income and other tax considerations of acquiring, holding and disposing of our common stock.

Dividends

If we pay distributions on our common stock, those distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder s investment, up to such holder s tax basis in the common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below under the heading Gain on Disposition of Common Stock.

Dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder s country of residence. If we determine, at a time reasonably close to the date of payment of a distribution on our common stock, that the distribution will not constitute a dividend because we do not anticipate having current or accumulated earnings and profits, we intend not to withhold any U.S. federal income tax on the distribution as permitted by U.S. Treasury Regulations.

Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States, and, if an applicable income tax treaty so provides, that are attributable to a permanent establishment or a fixed base maintained by the non-U.S. holder within the United States, are generally exempt from the 30% withholding tax if the non-U.S. holder satisfies applicable certification and disclosure requirements. To obtain this exemption, a non-U.S. holder must provide us with a properly executed original and unexpired IRS Form W-8ECI properly certifying such exemption. However, such U.S. effectively connected income, net of specified deductions and credits, is taxed at the same graduated U.S. federal income tax rates applicable to U.S. persons (as defined in the Code). Any U.S. effectively connected income received by a non-U.S. holder that is a corporation may also, under certain circumstances, be subject to an additional branch profits tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder s country of residence.

A non-U.S. holder of our common stock who claims the benefit of an applicable income tax treaty between the United States and such holder s country of residence providing for a reduced withholding tax rate on dividends generally will be required to provide a properly executed IRS Form W-8BEN (or successor form) and satisfy applicable certification and other requirements. Non-U.S. holders are urged to consult their own tax advisors regarding their entitlement to benefits under a relevant income tax treaty.

A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim with the IRS.

Gain on Disposition of Common Stock

A non-U.S. holder generally will not be subject to U.S. federal income tax on gain recognized on a disposition of our common stock unless:

the gain is effectively connected with the non-U.S. holder s conduct of a trade or business in the United States, and, if an applicable income tax treaty so provides, the gain is attributable to a permanent establishment maintained by the non-U.S. holder in the United States; in these cases, the

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non-U.S. holder will be taxed on a net income basis at the regular graduated rates and in the manner applicable to U.S. persons, and, if the non-U.S. holder is a foreign corporation, an additional branch profits tax at a rate of 30%, or a lower rate as may be specified by an applicable income tax treaty, may also apply;

the non-U.S. holder is an individual present in the United States for 183 days or more in the taxable year of the disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty) on the net gain derived from the disposition; or

we are or were a U.S. real property holding corporation during a certain look-back period unless our common stock is regularly traded on an established securities market and the non-U.S. holder held no more than five percent of our outstanding common stock, directly or indirectly, during the shorter of the five-year period ending on the date of the disposition or the period that the non-U.S. holder held our common stock. Generally, a corporation is a U.S. real property holding corporation if the fair market value of its U.S. real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. We believe that we are not currently, and we do not anticipate becoming, a U.S. real property holding corporation for U.S. federal income tax purposes.

Information Reporting and Backup Withholding Tax

We must report annually to the IRS and to each non-U.S. holder the gross amount of the distributions on our common stock paid to such holder and the tax withheld, if any, with respect to such distributions. Non-U.S. holders may have to comply with specific certification procedures to establish that the holder is not a U.S. person (as defined in the Code) in order to avoid backup withholding at the applicable rate (currently 28% through December 31, 2012, and thereafter set to increase to 31%) with respect to dividends on our common stock. Generally, a holder will comply with such procedures if it provides a properly executed IRS Form W-8BEN or otherwise meets documentary evidence requirements for establishing that it is a non-U.S. holder, or otherwise establishes an exemption.

Information reporting and backup withholding generally will apply to the proceeds of a disposition of our common stock by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the holder certifies its status as a non-U.S. holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Non-U.S. holders should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them.

Copies of information returns may be made available to the tax authorities of the country in which the non-U.S. holder resides or is incorporated under the provisions of a specific treaty or agreement.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder can be refunded or credited against the non-U.S. holder s U.S. federal income tax liability, if any, provided that an appropriate claim is timely filed with the IRS.

Foreign Account Tax Compliance Act

The recently enacted Foreign Account Tax Compliance Act, or FATCA, will impose a 30% withholding tax on any withholdable payment to (i) a foreign financial institution, unless an exceptions applies. The most important exception is that such institution enters into an agreement with the U.S. government to collect and provide to the U.S. tax

authorities substantial information regarding U.S. account holders of such institution (which would include certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with United States owners) or (ii) a foreign entity that is not a financial institution, unless an exception applies. The most important exception is that such entity provides the withholding agent with a certification identifying the substantial U.S. owners of the entity, which generally

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includes any U.S. person who directly or indirectly owns more than 10% of the entity. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes.

Withholdable payments will include U.S.-source payments otherwise subject to nonresident withholding tax, and also include the entire gross proceeds from the sale of any equity or debt instruments of U.S. issuers (in either case to exclude payments made on obligations that were outstanding on March 18, 2012). The withholding tax will apply regardless of whether the payment would otherwise be exempt from U.S. nonresident withholding tax (e.g., under the portfolio interest exemption or as capital gain). The IRS is authorized to provide rules for coordinating the FATCA withholding regime with the existing nonresident withholding tax rules.

Under proposed regulations, this withholding will apply to U.S.-source payments otherwise subject to nonresident withholding tax made on or after January 1, 2014 and to the payment of gross proceeds from the sale of any equity or debt instruments of U.S. issuers made on or after January 1, 2015.

Federal Estate Tax

Common stock owned or treated as owned by an individual who is a non-U.S. holder (as specially defined for U.S. federal estate tax purposes) at the time of death will be included in the individual s gross estate for U.S. federal estate tax purposes and, therefore, may be subject to U.S. federal estate tax, unless an applicable estate tax or other treaty provides otherwise.

The preceding discussion of material U.S. federal tax considerations is for general information only. It is not tax advice. Prospective investors should consult their own tax advisors regarding the particular U.S. federal, state, local and non- U.S. tax consequences of purchasing, holding and disposing of our common stock, including the consequences of any proposed changes in applicable laws.

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UNDERWRITING

Merrill Lynch, Pierce, Fenner & Smith Incorporated is acting as representative of each of the underwriters named below. Subject to the terms and conditions set forth in an underwriting agreement among us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of shares of common stock set forth opposite its name below.

Underwriter	Number of Shares
Merrill Lynch, Pierce, Fenner & Smith Incorporated	2,612,500
BMO Capital Markets Corp.	1,162,500
Needham & Company, LLC	575,000
Wedbush Securities Inc.	575,000
ThinkEquity LLC	75,000
Total	5,000,000

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the shares, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officer s certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

An affiliate of OrbiMed Advisors LLC, which holds more than 5% of our common stock, has agreed to purchase an aggregate of $5.0 million in shares of our common stock in this offering at the initial public offering price. In addition, New Leaf Venture Partners, L.L.C., of which Dr. Akkaraju, our director nominee, is a managing director, and its affiliated funds have agreed to purchase an aggregate of $10.5 million in shares of our common stock in this offering at the initial public offering price.

Commissions and Discounts

The representative has advised us that the underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of $.63 per share. After the initial offering, the public offering price, concession or any other term of the offering may be changed.

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The following table shows the public offering price, underwriting discount and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional shares.

	Per Share	Without Option	With Option
Public offering price	$15.00	$75,000,000	$86,250,000
Underwriting discount	$1.05	$5,250,000	$6,037,500
Proceeds, before expenses, to us	$13.95	$69,750,000	$80,212,500

The expenses of the offering, not including the underwriting discount, are estimated at $1.5 million and are payable by us.

Option to Purchase Additional Shares

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus, to purchase up to 750,000 additional shares at the public offering price, less the underwriting discount. If the underwriters exercise this option, each will be obligated, subject to conditions contained in the underwriting agreement, to purchase a number of additional shares proportionate to that underwriter s initial amount reflected in the above table.

No Sales of Similar Securities

We, our executive officers and directors and substantially all of our other existing security holders have agreed not to sell or transfer any common stock or securities convertible into, exchangeable for, exercisable for, or repayable with common stock, for 180 days after the date of this prospectus without first obtaining the written consent of Merrill Lynch, Pierce, Fenner & Smith Incorporated. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly

offer, pledge, sell or contract to sell any common stock,
sell any option or contract to purchase any common stock,
purchase any option or contract to sell any common stock,
grant any option, right or warrant for the sale of any common stock,
lend or otherwise dispose of or transfer any common stock,
request or demand that we file a registration statement related to the common stock, or
enter into any swap or other agreement that transfers, in whole or in part, the economic consequence of ownership of any common stock whether any such swap or transaction is to be settled by delivery of shares or other securities, in cash or otherwise.

This lock-up provision applies to common stock and to securities convertible into or exchangeable or exercisable for or repayable with common stock. It also applies to common stock owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition. In the event that either (x) during the last 17 days of the lock-up period referred to above, we issue an earnings release or material news or a material event relating to us occurs or (y) prior to the expiration of the lock-up period, we announce that we will release earnings results or become aware that material news or a material event will occur during the 16-day period beginning on the last day of the lock-up period, the restrictions described above shall continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the occurrence of the material news or material event; provided, however, that such extensions will apply only to the extent that the rules of the Financial Industry Regulatory Authority, Inc. relating to such extensions remain in effect.

Nasdaq Global Market Listing

Our common stock has been approved for listing on the Nasdaq Global Market, subject to notice of issuance, under the symbol ICPT. In order to meet the requirements for listing on that exchange, the underwriters have undertaken to sell a minimum number of shares to a minimum number of beneficial owners as required by that exchange.

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Before this offering, there has been no public market for our common stock. The initial public offering price was determined through negotiations between us and the representative. In addition to prevailing market conditions, the factors considered in determining the initial public offering price were:

the valuation multiples of publicly traded companies that the representative believes to be comparable to us,
our financial information,
the history of, and the prospects for, our company and the industry in which we compete,
an assessment of our management, its past and present operations, and the prospects for, and timing of, our future revenues,
the present state of our development, and
the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for the shares may not develop. It is also possible that after the offering the shares will not trade in the public market at or above the initial public offering price.

The underwriters do not expect to sell more than 5% of the shares in the aggregate to accounts over which they exercise discretionary authority.

Price Stabilization, Short Positions and Penalty Bids

Until the distribution of the shares is completed, the rules of the Securities and Exchange Commission may limit underwriters and selling group members from bidding for and purchasing our common stock. However, the representative may engage in transactions that stabilize the price of the common stock, such as bids or purchases to peg, fix or maintain that price.

In connection with the offering, the underwriters may purchase and sell our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering. Covered short sales are sales made in an amount not greater than the underwriters option to purchase additional shares described above. The underwriters may close out any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option granted to them. Naked short sales are sales in excess of such option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of shares of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representative has repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Similar to other purchase transactions, the underwriters purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might

otherwise exist in the open market. The underwriters may conduct these transactions on the Nasdaq Global Market, in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In

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addition, neither we nor any of the underwriters make any representation that the representative will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

Electronic Distribution

In connection with the offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail.

Other Relationships

Some of the underwriters and their affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They have received, or may in the future receive, customary fees and commissions for these transactions.

In addition, in the ordinary course of their business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Notice to Prospective Investors in the European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive, or each, a Relevant Member State, with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State, or the Relevant Implementation Date, no offer of shares may be made to the public in that Relevant Member State other than:

A. to any legal entity which is a qualified investor as defined in the Prospectus Directive;

B. to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representative; or

C. in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of shares shall require the Company or the representative to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

Each person in a Relevant Member State (other than a Relevant Member State where there is a Permitted Public Offer) who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed that (A) it is a qualified investor within the meaning of the law in that Relevant Member State implementing Article 2(1)(e) of the Prospectus Directive, and (B) in the case of any shares acquired by it as a financial intermediary, as that term is used in Article 3(2) of the Prospectus Directive, the shares acquired by it in the offering have not been acquired on behalf of, nor have they been acquired with a view to their offer or resale to, persons in any Relevant Member State other than qualified investors as defined in the Prospectus Directive, or in circumstances in which the prior consent of the representative has been given to the offer or resale. In the case of any

shares being offered to a financial intermediary as that term is used in Article 3(2) of the Prospectus Directive, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any shares to the public other than their offer or resale in a Relevant Member State to qualified investors as so defined or in circumstances in which the prior consent of the representative has been obtained to each such proposed offer or resale.

The Company, the representative and their affiliates will rely upon the truth and accuracy of the foregoing representation, acknowledgement and agreement.

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This prospectus has been prepared on the basis that any offer of shares in any Relevant Member State will be made pursuant to an exemption under the Prospectus Directive from the requirement to publish a prospectus for offers of shares. Accordingly any person making or intending to make an offer in that Relevant Member State of shares which are the subject of the offering contemplated in this prospectus may only do so in circumstances in which no obligation arises for the Company or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Directive in relation to such offer. Neither the Company nor the underwriters have authorized, nor do they authorize, the making of any offer of shares in circumstances in which an obligation arises for the Company or the underwriters to publish a prospectus for such offer.

For the purpose of the above provisions, the expression an offer to the public in relation to any shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase or subscribe the shares, as the same may be varied in the Relevant Member State by any measure implementing the Prospectus Directive in the Relevant Member State and the expression Prospectus Directive means Directive 2003/71/EC (including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member States) and includes any relevant implementing measure in the Relevant Member State and the expression 2010 PD Amending Directive means Directive 2010/73/EU.

Notice to Prospective Investors in the United Kingdom

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are qualified investors (as defined in the Prospectus Directive) (i) who have professional experience in matters relating to investments falling within Article 19 (5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or the Order, and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as relevant persons). This document must not be acted on or relied on in the United Kingdom by persons who are not relevant persons. In the United Kingdom, any investment or investment activity to which this document relates is only available to, and will be engaged in with, relevant persons.

Notice to Prospective Investors in Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, the Company, the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA (FINMA), and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

Notice to Prospective Investors in the Dubai International Financial Centre

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority, or DFSA. This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

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LEGAL MATTERS

The validity of the issuance of the common stock offered by us in this offering will be passed upon for us by Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., Boston, Massachusetts and for the underwriters by Goodwin Procter LLP, New York, New York.

EXPERTS

The consolidated financial statements of Intercept Pharmaceuticals, Inc. (a development stage enterprise) as of December 31, 2010 and December 31, 2011 and for each of the two years in the period ended December 31, 2011 and the information included in the cumulative from inception presentation for the period September 4, 2002 (Inception) to December 31, 2011, included in this prospectus have been so included in reliance on the report of KPMG LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

The information included in this prospectus in the cumulative from inception presentation for the period from September 4, 2002 (inception) through December 31, 2007 (not separately presented herein), has been so included in reliance on the report of EisnerAmper LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the Securities and Exchange Commission a registration statement on Form S-1 under the Securities Act, with respect to the common stock offered by this prospectus. This prospectus, which is part of the registration statement, omits certain information, exhibits, schedules and undertakings set forth in the registration statement. For further information pertaining to us and our common stock, reference is made to the registration statement and the exhibits and schedules to the registration statement. Statements contained in this prospectus as to the contents or provisions of any documents referred to in this prospectus are not necessarily complete, and in each instance where a copy of the document has been filed as an exhibit to the registration statement, reference is made to the exhibit for a more complete description of the matters involved.

You may read and copy all or any portion of the registration statement without charge at the public reference room of the Securities and Exchange Commission at 100 F Street, N.E., Washington, D.C. 20549. Copies of the registration statement may be obtained from the Securities and Exchange Commission at prescribed rates from the public reference room of the Securities and Exchange Commission at such address. You may obtain information regarding the operation of the public reference room by calling 1-800-SEC-0330. In addition, registration statements and certain other filings made with the Securities and Exchange Commission electronically are publicly available through the Securities and Exchange Commission s web site at *http://www.sec.gov.* The registration statement, including all exhibits and amendments to the registration statement, has been filed electronically with the Securities and Exchange Commission.

Upon completion of this offering, we will become subject to the information and periodic reporting requirements of the Securities Exchange Act and, accordingly, will be required to file annual reports containing financial statements audited by an independent public accounting firm, quarterly reports containing unaudited financial data, current reports, proxy statements and other information with the Securities and Exchange Commission. You will be able to

inspect and copy such periodic reports, proxy statements and other information at the Securities and Exchange Commission s public reference room, and the web site of the Securities and Exchange Commission referred to above.

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INTERCEPT PHARMACEUTICALS, INC.
(A Development Stage Company)

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Board of Directors and Stockholders
Intercept Pharmaceuticals, Inc.:

We have audited the accompanying consolidated balance sheets of Intercept Pharmaceuticals, Inc. and subsidiaries (a development stage enterprise) as of December 31, 2010 and 2011, and the related consolidated statements of operations and comprehensive loss, changes in stockholders equity, and cash flows for each of the years ended December 31, 2010 and 2011 and for the period from September 4, 2002 (inception) to December 31, 2011. These consolidated financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. The cumulative statements of operations and comprehensive loss, changes in stockholders equity, and cash flows for the period September 4, 2002 (inception) to December 31, 2011 include amounts for the period from September 4, 2002 (inception) to December 31, 2007, which were audited by other auditors whose report has been furnished to us, and our opinion, insofar as it relates to the amounts included for the period September 4, 2002 through December 31, 2007 is based solely on the report of other auditors.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, based on our audits and the report of other auditors, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Intercept Pharmaceuticals, Inc. and subsidiaries (a development stage enterprise) as of December 31, 2010 and 2011, and the results of their operations and their cash flows for each of the years ended December 31, 2010 and 2011 and for the period September 4, 2002 (inception) to December 31, 2011, in conformity with U.S. generally accepted accounting principles.

/s/ KPMG LLP
New York, New York
June 20, 2012, except as to note 1, which is as of September 26, 2012

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Intercept Pharmaceuticals, Inc.

We have audited the consolidated statements of operations and comprehensive loss, changes in stockholders equity and cash flows of Intercept Pharmaceuticals, Inc. and subsidiary (a development stage company) (the Company) for the period from September 4, 2002 (inception) through December 31, 2007. The consolidated statements of operations and comprehensive loss and cash flows for this period are not presented separately herein. The consolidated financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company s internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements enumerated above present fairly, in all material respects, the consolidated results of operations and consolidated cash flows of Intercept Pharmaceuticals, Inc. and subsidiary (a development stage company) for the period from September 4, 2002 (inception) through December 31, 2007 (not presented separately herein) in conformity with accounting principles generally accepted in the United States of America.

/s/ EisnerAmper LLP

New York, New York
August 31, 2012

Except for the last paragraph of note 1
as to which the date is September 26, 2012

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INTERCEPT PHARMACEUTICALS, INC.
(A Development Stage Company)

Consolidated Balance Sheets

	December 31, 2010	2011	June 30, 2012 (Unaudited)	Pro Forma June 30, 2012 (Unaudited)
Assets				
Current assets:				
Cash and cash equivalents	$15,423,746	$17,707,476	$9,947,233	$39,747,233
Certificates of deposit	72,087	200,775	78,874	78,874
Prepaid expenses and other assets	365,421	995,843	1,681,970	1,681,970
Total current assets	15,861,254	18,904,094	11,708,077	41,508,077
Fixed assets, net	876,446	311,366	175,991	175,991
Security deposits	380,330	254,869	261,023	261,023
Total assets	$17,118,030	$19,470,329	$12,145,091	$41,945,091
Liabilities				
Current liabilities:				
Accounts payable, accrued expenses, and other liabilities	$1,587,432	$1,504,198	$3,577,583	$3,577,583
Short-term portion of warrant liability	127,768		286,936	286,936
Short-term portion of deferred revenue		2,446,107	1,739,408	1,739,408
Short-term portion of capital leases	255,590	81,762		
Total current liabilities	1,970,790	4,032,067	5,603,927	5,603,927
Long-term liabilities:				
Long-term portion of deferred revenue		12,162,163	11,351,353	11,351,353
Long-term portion of warrant liability	6,752,935	5,835,877	4,569,466	4,992,910
Long-term portion of capital leases	75,839			
Total liabilities	8,799,564	22,030,107	21,524,746	21,948,190
Stockholders equity (deficit):				
Series A preferred stock. Authorized 13,888,889 shares, par value $0.001 per share, issued, and outstanding 13,888,889 shares, actual; 0 shares issued and outstanding, pro forma; liquidation preference of $1.80 per share plus accumulated dividends ($5,412,329 at December 31, 2011 and $6,160,274 at June 30, 2012), none pro forma	13,889	13,889	13,889	
Series B preferred stock. Authorized 13,888,889 shares, par value $0.001 per share, issued, and outstanding 13,888,889 shares,	13,889	13,889	13,889	

actual; 0 shares issued and outstanding, pro forma; liquidation preference of $1.80 per share plus accumulated dividends ($2,901,370 at December 31, 2011 and $3,649,315 at June 30, 2012), none pro forma				
Series C preferred stock. Authorized, issued and outstanding 15,000,000 shares; par value $0.001 per share; liquidation preference $2.00 per share; none pro forma				
Common stock. Authorized 57,000,000 shares, par value $0.001 per share, 3,329,666 shares issued and outstanding, actual; 10,733,483 shares issued and outstanding, pro forma	3,330	3,330	3,330	10,734
Additional paid-in capital	70,268,138	72,133,893	72,895,196	102,292,126
Accumulated other comprehensive loss	(178,155)	(184,500)		
Accumulated deficit during development stage	(61,802,625)	(74,540,279)	(82,305,959)	(82,305,959)
Total stockholders equity (deficit)	8,318,466	(2,559,778)	(9,379,655)	19,996,901
Total liabilities and stockholders equity (deficit)	$17,118,030	$19,470,329	$12,145,091	$41,945,091

* The unaudited pro forma balance sheet gives effect to the conversion of 15,000,000 shares of preferred stock issued on August 9, 2012 into 2,596,143 shares of the Company s common stock and the receipt of net proceeds of $29.8 million (see note 15).

See accompanying notes to consolidated financial statements.

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INTERCEPT PHARMACEUTICALS, INC.
(A Development Stage Company)

Consolidated Statements of Operations and Comprehensive Loss

See accompanying notes to consolidated financial statements.

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INTERCEPT PHARMACEUTICALS, INC.
(A Development Stage Company)

Consolidated Statements of Changes in Stockholders Equity
For the Period From September 4, 2002 (Inception) Through June 30, 2012

	Series A Preferred Stock		Series B Preferred Stock		Common Stock		Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Accumulated Other Comprehensive Gain (Loss)	Stoc Equ (De
	Shares	Amount	Shares	Amount	Shares	Amount				
alization September		$		$	949,035	$949	$26,468	$	$	$27
n November					60,576	61	1,689			1,7
n October 1,					112,498	112	3,138			3,2
of founders tober 27,					(550,960)	(551)	(15,366)			(1
ement from 2003 y 5, 2004					392,163	392	2,832,088			2,8
November					51,922	52	374,948			37
ement May					2,087,091	2,087	20,497,913			20
of notes May					160,637	161	1,341,088			1,3
ns, legal, osts for ement							(1,500,138)			(1
on: d							604,372			60

						494,685			49
stock				6,129	6	17,699			17
warrants				51,922	52	374,948			37
rehensive								84,978	84
the period 4, 2002 cember 31,							(18,656,010)		(1
December 31,	0	0		3,321,013	3,321	25,053,532	(18,656,010)	84,978	6,4
on: ad						682,025			68
						127,359			12
ement May	13,888,889	13,889				24,986,111			25
ns, legal, osts						(749,075)			(74
rehensive								(155,784)	(1
							(13,704,870)		(1
December 31,	13,888,889	13,889		3,321,013	3,321	50,099,952	(32,360,880)	(70,806)	17
on: ad						908,375			90
						53,425			53
effect of adjustment						(2,187,680)			(2
stock				8,653	9	24,991			25
rehensive								(7,314)	(7
							(14,354,522)		(14
December 31,	13,888,889	13,889		3,329,666	3,330	48,899,063	(46,715,402)	(78,120)	2,
on: ad						1,604,117			1,6
						88,768			88
ement 2010			13,888,889	13,889		19,787,894			19
ns, legal, osts						(111,704)			(1
rehensive								(100,035)	(1

								(15,087,223)		(1
December 31,	13,888,889	13,889	13,888,889	13,889	3,329,666	3,330	70,268,138	(61,802,625)	(178,155)	8,3

See accompanying notes to consolidated financial statements.

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INTERCEPT PHARMACEUTICALS, INC.
(A Development Stage Company)

Consolidated Statements of Changes in Stockholders Equity (continued)
For the Period From September 4, 2002 (Inception) Through June 30, 2012

See accompanying notes to consolidated financial statements.

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INTERCEPT PHARMACEUTICALS, INC.
(A Development Stage Company)

Consolidated Statements of Cash Flows

See accompanying notes to consolidated financial statements.

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INTERCEPT PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Business

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.

In 2008, Genextra S.p.A. (Genextra), an Italian biopharmaceutical holding company, acquired preferred stock that have voting rights and are convertible into shares of common stock (see note 9). As a result of this transaction, coupled with Genextra s previously held common stock interest, Genextra gained a controlling interest in Intercept. These consolidated financial statements do not reflect Genextra s accounting basis in Intercept.

The Company has its administrative headquarters in New York, New York and an office in San Diego, California. Prior to April 2012, the Company operated a wholly-owned subsidiary in Italy where much of its bile acid receptor research was conducted. This subsidiary is currently in the process of being liquidated; however, the Company is continuing its research through its collaboration with Servier (see note 3). Although Intercept Italia S.R.L. is currently in liquidation and essentially inactive, the Company does not intend to liquidate this subsidiary for some time because it acts as the Company s legal representative for Phase 3 clinical trials in the European Union to satisfy European Union regulatory requirements. Intercept was incorporated in Delaware in September 2002.

On September 13, 2012, the board of directors of the Company approved, and on September 25, 2012 the stockholders of the Company approved, a one-for-5.7778 reverse stock split of the Company s outstanding common stock, which was effected on September 26, 2012. Stockholders entitled to fractional shares as a result of the reverse stock split 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.

2. Summary of Significant Accounting Policies

A. Basis of Presentation and Use of Estimates

The Company s 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 consolidated financial statements have been prepared assuming that the Company will continue as a going concern. The ability of the Company to become profitable depends on several factors, many of which are outside the Company s control. Such factors include the ability to obtain regulatory approval of product candidates and the ability to successfully commercialize any approved product candidate. The Company s lead product candidate, OCA, has completed three Phase 2 clinical trials and is currently being tested in three additional clinical trials. Therefore, the Company s product candidates still require significant research and development efforts. The extent to which the Company will be able to continue its research and development efforts will also partially be determined by factors outside the Company s control, such as the nature and extent of testing that will be required by the U.S. Food and Drug Administration (FDA) and equivalent agencies outside of the United States.

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INTERCEPT PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. Summary of Significant Accounting Policies (continued)

The Company is monitoring market conditions for opportunities to raise additional financing; however, there is no assurance that financing will be available to fund further research and development after current cash balances are depleted. The timing of research and development costs is largely controllable in the current stages of development, and management is focused on actively managing its resources. Management believes that the Company s current cash and cash equivalents and short-term investments will be adequate to finance the Company s operations through 2012.

B. Unaudited Financial Information

The accompanying interim balance sheet as of June 30, 2012, statements of operations and of cash flows for the six months ended June 30, 2011 and 2012 and for the period from inception (September 4, 2002) through June 30, 2012 and the statement of stockholders equity (deficit) for the six months ended June 30, 2012 and for the period from inception (September 4, 2002) through June 30, 2012 are unaudited. The 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 as of June 30, 2012 and the results of its operations and cash flows for the six months ended June 30, 2011 and 2012 and for the period from inception (September 4, 2002) through June 30, 2012. The financial data and other information disclosed in these notes related to the six month periods ended June 30, 2011 and 2012 and for the period from inception (September 4, 2002) through June 30, 2012 are unaudited. The results for the six months ended June 30, 2012 and for the period from inception (September 4, 2002) through June 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.

C. Unaudited Pro Forma Information

In June 2012, the Company s board of directors authorized the management of the Company to file a registration statement with the Securities and Exchange Commission (SEC) for the Company to sell shares of its common stock to the public. All of the preferred stock outstanding (see note 9) will convert into shares of common stock upon the completion of this offering. The unaudited pro forma balance sheet information at June 30, 2012 gives effect to the conversion of all outstanding shares of the preferred stock as of such date into common stock and the reclassification of certain warrants with registration rights upon the completion of this offering from stockholders equity to warrant liability. The unaudited pro forma balance sheet also gives effect to the conversion of 15,000,000 shares of preferred stock issued on August 9, 2012 into 2,596,143 shares of the Company s common stock and the receipt of net proceeds of $29.8 million (see note 15).

D. Segments

The Company has determined that it operates in one segment. The Company is a biopharmaceutical company focused on discovering, developing and commercializing treatments for chronic liver diseases utilizing its proprietary bile acid chemistry.

E. Principles of Consolidation

The consolidated financial statements include the accounts of Intercept and its subsidiary, Intercept Italia S.R.L., which is currently in the process of being liquidated. Although Intercept Italia S.R.L. is currently in liquidation and essentially inactive, the Company does not intend to liquidate this subsidiary for some time because it acts as the Company s legal representative for Phase 3 clinical trials in the European Union to satisfy European Union regulatory requirements. All intercompany balances and transactions have been eliminated in consolidation.

F. Reclassification

Certain amounts shown in prior years consolidated financial statements have been reclassified to conform to the current year consolidated financial statement presentation.

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INTERCEPT PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. Summary of Significant Accounting Policies (continued)

G. Cash and Cash Equivalents

The Company considers all highly liquid securities with a maturity of three months or less at acquisition to be cash equivalents.

H. Certificates of Deposit

Certificates of deposit have original maturities of less than one year; however, amounts restricted for the payment of long-term capital lease obligations are classified as long-term assets. Certificates of deposit are recorded at amortized cost.

I. Concentration of Credit Risk

Concentration of credit risk exists with respect to cash and cash equivalents. The Company maintains its cash and cash equivalents with federally insured financial institutions, and at times the amounts may exceed the federally insured deposit limits. To date, the Company has not experienced any losses on its deposits of cash and cash equivalents.

J. Fair Value of Financial Instruments

The carrying amounts of the Company s receivables and payables approximate their fair value due to their short maturities. See note 8 for details on other financial assets and liabilities.

K. Fixed Assets

Fixed assets are recorded at cost, net of depreciation. Depreciation is recorded using the straight-line method over the estimated useful lives of three to seven years for equipment and seven years for furniture and fixtures. Leasehold improvements are amortized over the shorter of the asset s useful life or the life of the lease term. Expenditures for maintenance and repairs are charged to expense as incurred.

L. Impairment of Long-Lived Assets

Long-lived assets consist of fixed assets. The Company evaluates long-lived assets for impairment losses on long-lived assets used in operations when events and circumstances indicate that the carrying amount of an asset or group of assets may not be fully recoverable.

M. Revenue Recognition

All of the Company s revenue during the periods covered by these financial statements has been derived from its research and development and licensing collaborations. These agreements include non-refundable up-front fees and the potential for research, development, regulatory and commercial milestone fees, as well as royalties on product sales of licensed products, if and when such product sales occur. To date, the Company has received only up-front fees from its collaborations.

The Company evaluates all deliverables within an arrangement to determine whether or not they provide value on a stand-alone basis. Based on this evaluation, the deliverables are separated into units of accounting. The arrangement consideration that is fixed and determinable at the inception of the arrangement is allocated to the separate units of accounting based on relative fair value. The Company may exercise significant judgment in determining whether a deliverable is a separate unit of accounting, as well as in estimating the selling prices of such units of accounting. For each unit of accounting identified within an arrangement, the Company determines the period over which the performance obligation occurs and recognizes the revenue using a straight-line method.

The Company accounts for the development, regulatory and sales milestones within an arrangement in accordance with FASB ASC Topic 605-28, milestone method of revenue recognition. FASB ASC Topic 605-28

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INTERCEPT PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. Summary of Significant Accounting Policies (continued)

allows for the recognition of consideration, which is contingent on the achievement of a substantive milestone, in its entirety in the period the milestone is achieved. Each future milestone is considered substantive if each milestone (i) relates solely to the past performance of the intellectual property to achieve the milestone; (ii) is reasonable relative to all of the deliverables and payment terms in the arrangement; and (iii) is commensurate with either the Company s performance or the enhanced value of the intellectual property as a result of a specific outcome resulting from the Company s performance.

N. Research and Development

Research and development costs that do not have alternative future use are charged to expense as incurred. This includes the cost of conducting clinical trials, compensation and related overhead for employees and consultants involved in research and development and the cost of materials purchased for research and development.

O. Stock-Based Compensation

The Company has a compensation plan known as the Amended and Restated 2003 Stock Incentive Plan (2003 Plan). Under the 2003 Plan, restricted stock, stock options and other stock-related awards may be granted to the Company s directors, officers, employees and consultants. Stock options are granted at exercise prices not less than the fair market value of the Company s common stock at the dates of grant.

The Company utilizes the Black-Scholes option-pricing model for determining the estimated fair value of awards. Key inputs and assumptions include the expected term of the option, stock price volatility, risk-free interest rate, dividend yield, stock price and exercise price. Many of the assumptions require significant judgment and any changes could have a material impact in the determination of stock-based compensation expense. The Company estimates forfeitures when recognizing compensation expense and adjusts forfeiture estimates over the vesting period based on actual or anticipated forfeitures.

The Company recognizes stock-based compensation expense on a straight-line basis over the requisite service period of the individual grants, which is generally the vesting period, based on the estimated grant date fair values. Generally, stock options granted to employees fully vest four years from the grant date and have a term of ten years.

P. 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. Upon completion of this offering, these warrants will be reclassified as liabilities and warrant revaluation income (expense) will be recorded in the statement of operations. 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 that uses the inputs detailed in note 7 and the contractual terms of the warrants. 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 bionomial 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

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INTERCEPT PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. Summary of Significant Accounting Policies (continued)

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.

Q. 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 June 30, 2012, the Company had available net operating loss carryforwards to reduce future taxable income of approximately $55.0 million and $63.9 million (unaudited), respectively, for tax reporting purposes. These carryforwards expire between 2024 and 2032. The ability of the Company to utilize its net operating losses in future years is subject to limitation in accordance with provisions of Section 382 of the Internal Revenue Code due to previous ownership changes; however, these changes have not resulted in material limitations to the Company s ability to utilize the net operating losses. The Company s combined federal, state and city deferred tax asset of approximately $26.6 million, $32.1 million, and $35.8 million (unaudited) at December 31, 2010, December 31, 2011 and June 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.

R. Net Loss per Share and Unaudited Pro Forma Net Loss per Share

Basic net loss per share is calculated by dividing net loss attributable to common stockholders by the weighted average shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting weighted average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method. For purposes of the diluted net loss per share calculation, preferred stock, stock options and warrants are considered to be common stock equivalents but are excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive and, therefore, basic and diluted net loss per share were the same for all periods presented.

The calculations for the unaudited pro forma basic and diluted net loss per share assume the conversion of all outstanding shares of preferred stock into shares of common stock, as if the conversions had occurred at

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INTERCEPT PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. Summary of Significant Accounting Policies (continued)

the beginning of the period. The unaudited pro forma net loss used in the calculations of unaudited pro forma basic and diluted net loss per share has been adjusted to remove the cumulative preferred stock dividends.

S. Recent Accounting Pronouncements

In June 2011, the FASB issued an amendment to the accounting guidance for presentation of comprehensive income. Under the amended guidance, a company may present the total of comprehensive income, the components of net income and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. In either case, a company is required to present each component of net income along with total net income, each component of other comprehensive income along with a total for other comprehensive income and a total amount for comprehensive income. The amendment is effective for fiscal years ending, and interim periods within those years, beginning after December 15, 2011, and is applied retrospectively. The adoption of this update did not have a material impact on the Company s consolidated financial statements as the Company previously reported comprehensive income as a single continuous statement.

In May 2011, the FASB issued amended guidance on fair value measurements. This newly issued accounting standard clarifies the application of certain existing fair value measurement guidance and expands the disclosures for fair value measurements that are estimated using significant unobservable (Level 3) inputs. This accounting standard was effective on a prospective basis for annual and interim reporting periods beginning on or after December 15, 2011. The adoption of this standard has not had a material impact on our financial position or results of operations.

3. Significant Agreements

Dainippon Sumitomo Pharma Co, Ltd. (DSP)

In March 2011, the Company entered into an exclusive license agreement with DSP to research, develop and commercialize OCA as a therapeutic for the treatment of PBC and 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 year ended December 31,

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3. Significant Agreements (continued)

2011 and the six months ended June 30, 2012, the Company recorded revenue of $1.2 million and $0.8 million (unaudited), respectively, in License Fees 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 June 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 (Servier)

In August 2011, the Company entered into a research collaboration agreement with Servier under which we 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 us royalties based on net sales of products developed under the agreement on a country-by-country basis. Servier is also obligated to pay us 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 year ended December 31, 2011 and the six months ended June 30, 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 the license does not have stand-alone value to Servier without the Company s technical expertise and committee participation during the initial 12-month period. The research portion of the collaboration may be extended by mutual

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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 year ended December 31, 2011 and the six months ended June 30, 2012, the Company recorded revenue of $589,000 and $707,000 (unaudited), respectively related to the Company s efforts under the Servier arrangement, which was recorded in License Fees in the Company s Consolidated Statement of Operations. 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 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 year ended December 31, 2011 and the six months ended June 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 June 30, 2012, the Company has recorded $486,000 and $472,000 (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 years ended December 31, 2010 and 2011 and for the six months ended June 30, 2011 and 2012 of $550,000, $138,000, $70,000 (unaudited) and $51,000 (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 we 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

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3. Significant Agreements (continued)

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 June 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 years ended December 31, 2010 and 2011 and for the six months ended June 30, 2011 and 2012 of $318,000, $266,000, $70,000 (unaudited) and $163,000 (unaudited), respectively.

TES Pharma SRL (TES)

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

The agreement 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 year ended December 31, 2011 and for the six months ended June 30, 2012 of $596,000 and $672,000 (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 nonalcoholic steatohepatitis 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 will be required to make an additional $1.25 million payment within 60 days of full enrollment of the FLINT trial,

which is expected to occur in 2012. The Company has recognized expense related to this contract for the years ended December 31, 2010 and 2011 and for the six months ended June 30, 2011 and 2012 of $500,000, $250,000, $168,000 (unaudited) and $1,982,000 (unaudited), respectively.

WIL Research Laboratories, LLC (WIL)

On October 2, 2007, the Company entered into a master laboratory services agreement with WIL Research Laboratories, LLC to perform certain research and laboratory services. The agreement was amended in October 2011. The agreement has a term ending on October 2, 2013, 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

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3. Significant Agreements (continued)

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 years ended December 31, 2010 and 2011 and for the six months ended June 30, 2011 and 2012 of $1,561,201, $1,520,421, $223,652 (unaudited) and $852,500 (unaudited), respectively.

4. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	December 31,		June 30,
	2010	2011	2012
	(In thousands)		
			(Unaudited)
Prepaid expenses	$ 48	$ 359	$ 347
Refundable tax credits	318	151	78
Contract receivable		486	472
Deferred financing costs			785
Prepaid expenses and other current assets	$ 366	$ 996	$ 1,682

5. Fixed Assets, Net

Fixed assets, net consisted of the following:

	Useful Lives (Years)	December 31,		June 30,
		2010	2011	2012
		(In thousands)		
				(Unaudited)
Laboratory equipment	5	$1,071	$1,046	$ 1,015
Office equipment	3	484	318	340
Purchased software	3	10		
Leasehold improvements	Over life of lease	670	178	178

Furniture and fixtures under capitalized lease		157	157	157
Furniture and fixtures	7	181	120	121
Subtotal fixed assets		2,573	1,819	1,811
Less: accumulated depreciation and amortization		(1,697)	(1,508)	(1,635)
Fixed assets, net		$876	$311	$ 176

Depreciation and amortization expense for the years ended December 31, 2010 and 2011 was $480,000 and $411,000, respectively. During 2011, the Company closed its facility in Italy and in August 2011, in connection with entering into the TES agreement (note 3), transferred its rights in its certain 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.

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6. Accounts Payable, Accrued Expenses and Other Liabilities

Accrued expenses and other liabilities consisted of the following:

	December 31,		June 30,
	2010	2011	2012
	(In thousands)		
			(Unaudited)
Accounts payable	$ 480	$ 604	$ 1,101
Accrued employee compensation	776	728	546
Accrued contracted services & other	331	172	1,931
Accounts payable, accrued expenses and other liabilities	$ 1,587	$ 1,504	$ 3,578

7. Warrants to Purchase Common Stock

The Company s activity related to warrants to purchase shares of common stock of the Company is noted in the table below.

	Warrants to Purchase Common Stock	Weighted Average Exercise Price	Expiration	Balance Sheet Classification
Warrants issued in 2003[1]	2,163	$ 2.89	10/24/2013	Liability
Warrants issued in 2003	2,163	8.67	10/27/2013	Equity
Warrants issued in 2004[1]	117,642	2.89	10/27/2013	Liability
Warrants issued in 2004[1]	19,609	2.89	5/4/2014	Liability
Warrants issued in 2004	117,640	8.67	10/27/2013	Equity
Warrants issued in 2005	138,461	7.22	Expired	Equity
Warrants issued in 2006[2]	86,538	9.82	Expired	Liability
Warrants issued in 2006	20,481	9.82	Expired	Equity
Warrants exercised in 2007	(51,922)	7.22		
Warrants issued in 2008[2]	108,169	10.40	5/23/2013	Liability
Warrants issued in 2010[2]	865,381	10.40	1/25/2015	Liability
Warrants expired in 2010	(86,539)	7.22		
Warrants issued and outstanding as of December 31, 2010	1,339,786			
Warrants expired in 2011	(107,019)	9.82		

Warrants issued and outstanding as of December 31, 2011	1,232,767	9.38
Warrants expired in 2012		
Warrants issued and outstanding as of June 30, 2012 (unaudited)	1,232,767	$ 9.38

(1) Each of these warrants contains anti-dilution provisions providing for adjustments to the exercise price upon the issuance of shares of common stock for no consideration or at a price less than the exercise price pursuant to a merger, asset acquisition or other business combination where a third party acquires a majority equity interest in or all or substantially all of the assets of the Company. If such a lower-priced issuance occurs, the exercise price of these warrants will be reduced to the price at which the common stock is issued.

(2) Each of these warrants contains anti-dilution provisions providing for adjustments to the exercise price upon the issuance of shares of common stock for no consideration or at a price less than the exercise price, excluding certain shares of common stock issuable upon exercise of options, warrants or conversion of convertible securities. If such a lower-priced issuance occurs, the exercise price of the warrants will be reduced based on a weighted average of the difference between the exercise price of the warrants and the issuance price of the shares.

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7. Warrants to Purchase Common Stock (continued)

Certain warrants (denoted with (1) or (2) in the table above) include a provision that provides for a reduction in the warrant exercise price if the Company subsequently issues additional shares of common stock for consideration per share less than the warrant exercise price. As a result of these provisions, the warrants have been deemed to be derivative instruments that require liability classification and mark-to-market accounting pursuant to an accounting standard that became effective on January 1, 2009. The fair values of the warrants are reflected in the accompanying balance sheets and were determined using the Black-Scholes option-pricing model using the following weighted average assumptions:

	December 31,		June 30,	
	2010	2011	2011 (Unaudited)	2012
Stock price	$ 8.67	$ 8.67	$ 8.67	$ 8.96
Expected dividend				
Expected term	3.70	2.78	3.51	2.52
Risk free interest rate	1.43 %	0.33 %	1.64 %	0.47 %
Expected volatility	108.54 %	102.76 %	115.98 %	86.85 %

The expected term is based on the remaining term of each warrant valued. The risk free interest rate is based on the rate for U.S. Treasury securities for the expected term of each warrant valued. The expected volatility was estimated based on historical volatility information of peer companies that are publicly available.

Registration Rights

The Company has agreed to file a registration statement registering the shares underlying the outstanding warrants issued in 2003 and 2004 within 90 days after the completion of its contemplated initial public offering (see note 2C) unless such shares are eligible for sale under Rule 144. This requirement to maintain effectiveness of the registration of underlying common stock for warrants representing 117,640 shares will require liability classification upon an initial public offering as the ability to maintain an effective registration statement is outside the Company s control and therefore could require cash settlement of these warrants. The fair value of these warrants as of June 30, 2012 is approximately $424,000. The ability to maintain an effective registration statement is outside of the Company s control and therefore could require cash settlement of these warrants.

Holders of warrants representing 41,176 shares of common stock issued in 2008 and the holder of all of the warrants issued in 2010 have registration rights under the Company s second amended and restated stockholders agreement dated January 20, 2010. Pursuant to the second amended and restated stockholders agreement, certain holders of the Company s preferred stock, warrants and/or common stock have the right to demand the filing of a registration statement for the registration of their shares of capital stock after the earlier of four years from the date of the second

amended and restated stockholders agreement or six months after the closing of the Company s initial public offering. In the event that the Company proposes to register any of its securities under the Securities Act of 1933, as amended (the Securities Act), either for its own account or for the account of other security holders, these holders are entitled to notice of such registration and are entitled to certain piggyback registration rights allowing the holder to include their shares of capital stock in such registration. The Company may, in certain circumstances, defer such registrations, and any underwriters will have the right, subject to certain limitations, to limit the number of shares included in such registrations. Further, these holders may require the Company to register for resale all or a portion of their shares of capital stock on a registration statement on Form S-3 once the Company is eligible to use Form S-3, subject to certain conditions and limitations.

See note 15 for subsequent events relating to the Company s amended and restated stockholders agreement.

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8. Fair Value Measurements

As referenced in note 2, 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, 2010				
Liabilities:				
Warrants to purchase common stock	$ (6,881)	$	$	$ (6,881)
Total liabilities	$ (6,881)	$	$	$ (6,881)
December 31, 2011				
Liabilities:				
Warrants to purchase common stock	$ (5,836)	$	$	$ (5,836)
Total liabilities	$ (5,836)	$	$	$ (5,836)
June 30, 2012 (unaudited)				

Liabilities:			
Warrants to purchase common stock	$ (4,856)	$	$ (4,856)
Total liabilites	$ (4,856)	$	$ (4,856)

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.

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9. Stockholders Equity and Preferred Stock (continued)

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. See note 7 for details on these warrants.

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.

Dividends

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

Voting

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

Liquidation

After payment to the preferred stockholders of their liquidation preferences, holders of common stock are entitled to share ratably in all remaining assets of the Company.

Preferred Stock

In May 2008, to effectuate the sale of Series A preferred stock, the Company amended and restated its Certificate of Incorporation in its entirety to increase the number of shares of preferred stock it was authorized to issue to 13,888,889 shares and to designate such shares as Series A preferred stock. In May 2008, 13,888,889 shares of Series A preferred stock were sold to Genextra 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.

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9. Stockholders Equity and Preferred Stock (continued)

See note 15 for subsequent events relating to the Company s preferred stock.

Voting

The holders of the preferred stock are entitled to vote, together with the holders of common stock, on all matters submitted to stockholders for a vote. Each preferred stockholder is entitled to the number of votes equal to the number of shares of common stock into which the shares of such holders preferred stock is convertible at the time of such vote.

Dividends

Both the Series A and B preferred stock accrue dividends at an annual rate of $0.108 per share (cumulative dividends of $5.4 million for the Series A preferred stock and $2.9 million for the Series B preferred stock had accrued at December 31, 2011). The dividends are only payable upon the occurrence of certain events as defined in the restated Certificate of Incorporation.

Liquidation

In the event of liquidation, dissolution or winding up of the Company, holders of the Series A and B preferred stock will be entitled to be paid, before any distribution is made to the holders of common stock, an amount equal to the greater of (a) $1.80 per share of preferred stock, plus any accrued but unpaid dividends, together with any other dividends declared, and (b) such amount per share as would have been payable had all such shares of preferred stock been converted to common stock immediately prior to such event. In the event that assets of the Company are insufficient to permit payment of the above-mentioned amounts, holders will share ratably in any distribution of the remaining assets and funds of the Company in proportion to the respective amounts which would otherwise be payable under these circumstances in the order of liquidation preference.

Conversion

The shares of preferred stock are convertible, at the option of the holder thereof, at any time, without the payment of additional consideration, into such number of fully paid and nonassessable shares of common stock as is determined by dividing the original issue price ($1.80 share) by the conversion price (initially set at $10.40 share after giving effect to the reverse stock split) in effect at the time of conversion. The conversion price is subject to adjustment in certain circumstances.

10. 2003 Stock Incentive Plan

In 2003, the Board of Directors and the stockholders of the Company approved the 2003 Plan, which provides for the granting of equity awards to officers, directors, employees, advisors, and consultants of the Company. The types of awards that may be granted under the 2003 Plan include qualified incentive stock options, nonstatutory stock options, restricted stock and other stock-based awards. 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. See note 15 for subsequent events relating to the 2003 Plan. Most options are scheduled to vest over a period of up to four years.

The estimated fair value of the options that have been granted is determined utilizing the Black-Scholes option-pricing model at the date of grant. For the years ended December 31, 2010 and 2011 and for the six months ended June 30, 2011 and June 30, 2012, the Company granted to employees and directors 428,353, 214,962, 0 (unaudited) and 0 (unaudited) options, respectively, with an aggregate fair market value of $3.1 million, $1.5 million, $0 (unaudited) and $0 (unaudited), respectively. The Company recorded option expense for employees and directors of $1.6 million, $1.8 million, $723,000 (unaudited) and $755,000 (unaudited) for the years ended December 31, 2010 and 2011 and the six months ended June 30, 2011 and 2012, respectively. There were 256,585 and 60,411 shares available for grant at December 31, 2010 and 2011, respectively. As of December 31, 2011, $3.0 million of total unrecognized compensation cost related to unvested share options is expected to be recognized over a weighted-average period of 2.28 years.

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10. 2003 Stock Incentive Plan (continued)

For the years ended December 31, 2010 and 2011 and for the six months ended June 30, 2011 and June 30, 2012, the Company granted to consultants 27,691, 6,056, 0 (unaudited) and 0 (unaudited) options, respectively, and recorded option expense associated with these grants of $89,000, $86,000, $29,000 (unaudited) and $6,000 (unaudited), respectively.

The Company estimated the fair value of stock options in the periods presented using a Black-Scholes option-pricing model utilizing the following assumptions:

	Years Ended December 31,			
	2010		2011	
Volatility	112%	113%	107%	113%
Expected term (in years)	5.6	5.7	5.0	6.0
Risk-free interest rate	1.6%	1.7%	1.1%	1.4%
Expected dividend yield		%		%
Stock price	$ 8.67		$ 8.67	

The common stock price was determined based on a valuation of the Company s common stock. The risk free interest rates was based on the rate for U.S. Treasury securities at the date of grant with maturity dates approximately equal to the expected life at the grant date. The expected life was based on the simplified method in accordance with SEC Staff Accounting Bulletin Nos. 107 and 110 as the Company s shares are not publicly traded. The expected volatility was estimated based on historical volatility information of peer companies that are publicly available.

The Company s combined outstanding employee and non-employee option activity for the period from December 31, 2009 through December 31, 2011 is summarized as follows:

	Number of Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value
Outstanding at December 31, 2009	674,537	$ 9.24	$ 350,000
Granted	456,049	$ 8.67	
Exercised			
Cancelled/forfeited	(2,596)	$ 9.82	350,000
Outstanding at December 31, 2010	1,127,990	$ 9.01	350,000
Granted	221,018	$ 8.67	
Exercised			

Cancelled/forfeited	(39,644)	$ 8.72	30,000
Outstanding at December 31, 2011	1,309,364	$ 8.98	350,000
Exercisable at December 31, 2011	865,068	$ 9.07	$ 350,000

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the underlying options and the deemed fair value of the Company s common stock for those shares that had exercise prices lower than the deemed fair value of the Company s common stock.

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10. 2003 Stock Incentive Plan (continued)

The following table summarizes additional information about stock options outstanding:

December 31, 2010	Options Outstanding			Options Exercisable		
Exercise Price	Number of Shares	Weighted-Average Remaining Life	Aggregate Intrinsic Value	Number of Shares	Weighted-Average Remaining Life	Aggregate Intrinsic Value
$2.89	65,766	3.8	$ 380,000	65,766	3.8	$ 380,000
$8.67	456,049	9.6		114,003	9.6	
$9.82	454,739	7.3		317,327	6.9	
$10.11	7,787	6.2		7,787	6.2	
$10.41	143,649	7.1		102,144	7.1	
	1,127,990	8.0	$ 380,000	607,027		$ 380,000
Options exercisable and expected to become exercisable	1,127,990	8.0	$ 380,000			

December 31, 2011	Options Outstanding			Options Exercisable		
Exercise Price	Number of Shares	Weighted-Average Remaining Life	Aggregate Intrinsic Value	Number of Shares	Weighted-Average Remaining Life	Aggregate Intrinsic Value
$2.89	60,574	2.9	$ 350,000	60,574	2.9	$ 350,000
$8.67	671,442	9.0		286,733	8.8	
$9.82	425,912	6.2		375,069	6.1	
$10.11	7,787	5.2		7,787	5.2	
$10.41	143,649	6.1		134,905	6.1	
	1,309,364	7.5	$ 350,000	865,068		$ 350,000
Options exercisable and expected to become exercisable	1,309,364	7.5	$ 350,000			

11. QTDP

In 2010, the Company recognized other income related to the Qualifying Therapeutic Discovery Project (QTDP). The QTDP program was created by the United States Congress as part of the Patient Protection and Affordable Care Act and provided for reimbursement of certain costs paid or incurred during 2009 and 2010 directly related to the conduct of a QTDP. During the year ended December 31, 2010, the Company was awarded $489,000 related to this program, which is included in other income in the accompanying statement of operations.

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12. Commitment and Contingencies

Facility Leases

The Company leases general and administrative office space in New York, New York and San Diego, California pursuant to non-cancellable operating leases that expire in November 2013 and in December 2014, respectively. In addition, the Company leases office and research space in Perugia, Italy pursuant to a euro denominated operating lease that expires in July 2012. The terms of the lease provide for rental payments on a graduated scale, and the Company recognizes rent expense on a straight-line basis over the non-cancellable lease term and records the difference between cash rent payments and the recognition of rent expense as a deferred rent liability included in accrued expenses. The Company is required to pay its share of operating expenses, such as property taxes and building costs, and these amounts are not included in rent expense or minimum operating lease payments below. Rent expense under operating leases for facilities for the years ended December 31, 2010 and 2011, and the six months ended June 30, 2011 and June 30, 2012, was approximately $299,000, $291,000, $ 153,000 (unaudited) and $175,000 (unaudited), respectively. As of December 31, 2011, minimum operating lease payments under non-cancelable leases (as amended) are as follows:

Year Ending December 31,	Amount (In thousands)
2012	$ 293
2013	331
2014	213
Total future minimum operating lease payments	$ 837

Contingencies

The Company may become subject to claims and assessments from time to time in the ordinary course of business. Such matters are subject to many uncertainties and outcomes are not predictable with assurance. The Company accrues liabilities for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. As of December 31, 2010 and 2011 and June 30, 2012 (unaudited), the Company does not believe that any such matters, individually or in the aggregate, will have a material adverse effect on the Company s business, financial condition, results of operations or cash flows.

13. Related Party Transactions

During 2008, the Company retained the services of Jim Mervis, who at the time served as chairman of the board of directors, to assist with business development, resulting in general and administrative expense of $173,000 in 2008, which is included in our cumulative results for the period from September 4, 2002 (inception) through December 31,

2011.

13. Related Party Transactions 313

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14. Net Loss Per Share

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

	Years Ended December 31,		Six Months Ended June 30,	
	2010	2011	2011	2012
	(In thousands, except share and per share amounts)			
			(unaudited)	
Historical net loss per share				
Numerator:				
Net loss attributable to common stockholders	$(17,989)	$(15,738)	$(7,751)	$(9,266)
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	$(5.40)	$(4.73)	$(2.33)	$(2.78)
Pro forma net loss per share (unaudited)				
Numerator:				
Net loss attributable to common stockholders used to compute pro forma net loss per share, basic and diluted		(12,738)		(7,766)
Denominator:				
Weighted average shares outstanding, basic and diluted		3,329,666		3,329,666
Add: Shares issued upon conversion of Series A and Series B preferred stock		4,807,674		4,807,674
Series C preferred stock		2,596,143		2,596,143
Weighted average shares used in computing pro forma net loss per share, basic and diluted		10,733,483		10,733,483
Pro forma net loss per share, basic and diluted		$(1.19)		$(0.72)

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14. Net Loss Per Share (continued)

The following potentially dilutive securities have been excluded from the computations of diluted weighted average shares outstanding as of December 31, 2010 and 2011 and June 30, 2012, as they would have been anti-dilutive:

	December 31,		June 30,
	2010	2011	2012
	(In thousands)		
			(Unaudited)
Shares issuable upon conversion of preferred stock	4,808	4,808	4,808
Shares issuable pursuant to accumulated preferred stock dividend	613	959	1,132
Options	1,128	1,309	1,309
Warrants to purchase common stock	1,340	1,233	1,233
Total	7,889	8,309	8,482

15. Subsequent Events

Subsequent Events Through June 20, 2012

The Company has evaluated events from the audited balance sheet date through June 20, 2012, the date at which the consolidated financial statements were available to be issued.

Subsequent Events From June 21, 2012 Through September 26, 2012 (unaudited)

The Company has also evaluated subsequent events from June 21, 2012 through September 26, 2012.

Series C preferred stock transaction

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 (the Series C financing). 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.

The securities purchase agreement provides that the Series C preferred stock may be issued in two tranches consisting of 15,000,000 and 10,000,000 shares. The first tranche of Series C preferred stock was issued on August 9, 2012, and resulted in net proceeds of $29.8 million to the Company. The closing of the second tranche of Series C preferred stock will only occur if the Company does not complete an initial public offering of common stock on or prior to the one year anniversary of the closing of the first tranche. The investors have been granted certain demand and piggyback registration rights in respect of their securities. Under the securities purchase agreement, the Company has agreed to indemnify each purchaser of Series C preferred stock and its employees, agents, stockholders and affiliates, up to an aggregate amount equal to the purchase price of the Series C preferred stock until August 9, 2015, for any and all losses, judgments or damages sustained or incurred by or asserted against such indemnified party arising out of or in any way relating to any material breach of the Company s representations and warranties, the failure by the Company to fulfill any material obligation, agreement or covenant under the securities purchase agreement or the third amended and restated stockholders agreement, or any cost or expense, including reasonable legal fees incurred in connection with enforcing the rights of such indemnified party.

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INTERCEPT PHARMACEUTICALS, INC.
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15. Subsequent Events (continued)

1) Voting

In general, the holders of the Series C preferred stock are entitled to vote, together with the holders of common stock, on all matters submitted to stockholders for a vote. Each Series C preferred stockholder is entitled to the number of votes equal to the number of shares of common stock into which the shares of such holder s Series C preferred stock is convertible at the time of such vote.

2) Dividends

The Series C preferred stock accrue dividends at an annual rate of $0.12 per share. The dividends are payable only upon the occurrence of certain events as defined in the restated Certificate of Incorporation. No dividends on the Series A and Series B preferred stock will be payable unless all accrued and unpaid dividends on the Series C preferred stock have been paid.

3) Liquidation

In the event of liquidation, dissolution or winding up of the Company, holders of Series C preferred stock are entitled to be paid, before any distribution is made to the holders of Series A or B preferred stock or common stock, an amount equal to the greater of (a) $2.00 per share of Series C preferred stock, plus any accrued but unpaid dividends, together with any other dividends declared, and (b) such amount per share as would have been payable had all such shares of preferred stock been converted to common stock immediately prior to such event. In the event that assets of the Company are insufficient to permit payment of the above-mentioned amounts, the holders will share ratably in any distribution of the remaining assets and funds of the Company in proportion to the respective amounts which would otherwise be payable under these circumstances in the order of liquidation preference.

4) Conversion

The shares of Series C preferred stock are convertible, at the option of the holder thereof, at any time, without the payment of additional consideration, into such number of fully paid and nonassessable shares of common stock as is determined by dividing the original issue price ($2.00 per share) by the conversion price (set at $11.56 per share after giving effect to the reverse stock split) in effect at the time of conversion. The conversion price will be subject to adjustment in certain circumstances.

Under the Company s restated Certificate of Incorporation, all outstanding shares of the Company s preferred stock will be mandatorily and automatically converted into shares of the Company s common stock upon either (i) the closing of an underwritten public offering of shares of common stock at a price of at least $13.00 per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization

with respect to the common stock) pursuant to an effective registration statement under the Securities Act, resulting in at least $40,000,000 of gross proceeds, before underwriting discounts and commissions and expenses, to the Company or (ii) the date and time, or the occurrence of an event, specified by vote or written consent of the holders of outstanding shares of preferred stock representing at least 80% of the total number of shares of common stock into which the outstanding shares of preferred stock could be converted.

All outstanding shares of Series C preferred stock will be converted into shares of common stock upon the completion of this offering.

Registration Rights

On August 9, 2012, the Company entered into its third amended and restated stockholders agreement with certain holders of the Company s preferred stock, warrants and/or common stock. Pursuant to the third amended and restated stockholders agreement, the holders who are parties to the agreement have the right to demand the filing of a registration statement for the registration of their shares of capital stock after the earlier of four years from the date of the third amended and restated stockholders agreement or six months after the

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

15. Subsequent Events (continued)

closing of the Company s initial public offering. In the event that the Company proposes to register any of its securities under the Securities Act, either for its own account or for the account of other security holders, these holders will be entitled to notice of such registration and will be entitled to certain piggyback registration rights allowing the holder to include their shares of capital stock in such registration. The Company may, in certain circumstances, defer such registrations, and any underwriters will have the right, subject to certain limitations, to limit the number of shares included in such registrations. Further, these holders may require the Company to register for resale all or a portion of their shares of capital stock on a registration statement on Form S-3 once the Company is eligible to use Form S-3, subject to certain conditions.

2003 Stock Plan Amendment

On August 9, 2012, the 2003 Plan was amended to increase the maximum number of shares authorized for issuance by 519,229 shares.

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Through and including November 4, 2012 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

5,000,000 Shares

Common Stock

PROSPECTUS

BofA Merrill Lynch

BMO Capital Markets

Needham & Company

Wedbush PacGrow Life Sciences

ThinkEquity LLC

October 10, 2012