Danaos Corp
Form F-1/A
September 07, 2018

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As filed with the Securities and Exchange Commission on September 7, 2018

Registration No. 333-226096

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

PRE-EFFECTIVE AMENDMENT
NO. 1 to

Form F-1

REGISTRATION STATEMENT
UNDER THE SECURITIES ACT OF 1933

DANAOS CORPORATION

(Exact Name of Registrant as Specified in its Charter)

Republic of The Marshall Islands	**4412**	**Not Applicable**
(State or Other Jurisdiction of Incorporation or Organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

c/o Danaos Shipping Co. Ltd, Athens Branch
14 Akti Kondyli
185 45 Piraeus
Greece
011 030 210 419 6480

(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

Puglisi & Associates
850 Library Avenue, Suite 204
Newark, Delaware 19711
(302) 738-6680 (Phone)
(302) 738-7210 (Fax)

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies of all communications, including communications sent to agent for service, should be sent to:

Finnbarr D. Murphy **David A. Sirignano** **Morgan, Lewis & Bockius LLP** **101 Park Avenue** **New York, New York 10178** **United States of America** **Telephone: +1 (212) 309-6000**	**Evangelos Chatzis** **Chief Financial Officer** **c/o Danaos Shipping Co. Ltd, Athens Branch** **14 Akti Kondyli** **185 45 Piraeus** **Greece**	**James A. McDonald** **Maria Protopapa** **Skadden, Arps, Slate, Meagher and Flom (UK) LLP** **40 Bank Street** **London E14 5DS** **United Kingdom**

Facsimile: +1 (212) 309-6001 **Telephone: +30 210 419 6480** **Telephone: +44 20 7519 7000**
Facsimile: +30 210 419 6489 **Facsimile: +44 20 7519 7070**

Approximate date of commencement of proposed sale to the public:
From time to time after this registration statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ý

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933. o

Emerging growth company o

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. o

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The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered(1)	Proposed maximum offering price per common share(2)	Proposed Maximum Aggregate Offering Price(2)	Amount of Registration Fee
Common stock, $0.01 par value per share	99,342,271	$1.75	$173,848,974.25	$21,644.20(*)
Preferred stock purchase rights(3)				

(1) Pursuant to Rule 416 under the Securities Act of 1933, as amended (the "Securities Act"), the shares of common stock being registered hereunder include such indeterminate number of shares as may be issuable as a result of stock splits, stock dividends or similar transactions.

(2) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(c) under the Securities Act and based on the average of the high and low sale prices of the Company's common stock on June 29, 2018, as reported on the New York Stock Exchange.

(3) The preferred stock purchase rights are initially attached to and trade with the shares of our common stock registered hereby. Value attributed to such rights, if any, is reflected in the market price of our common stock.

* Previously paid.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED SEPTEMBER 7, 2018

Preliminary Prospectus

Danaos Corporation

99,342,271 Shares of Common Stock

This prospectus relates to the resale, from time to time, of up to 99,342,271 shares of common stock of Danaos Corporation (referred to herein as "we", "us", "Danaos" or the "Company"), being offered by the selling stockholders identified herein. The selling stockholders may sell their shares, from time to time, in one or more offerings, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices. The selling stockholders may sell shares in a manner including, but not limited to, regular brokerage transactions, in transactions directly with market makers or investors, in privately negotiated transactions or through agents or underwriters they may select from time to time. See "*Plan of Distribution*" for more information on the methods of sale that may be used by the selling stockholders.

We are not offering any common stock for sale under this prospectus, and we will not receive any proceeds from the sale of the common stock by the selling stockholders.

We may amend or supplement this prospectus from time to time by filing amendments or supplements as required. You should read this entire prospectus, including the information incorporated by reference into this prospectus, and any amendments or supplements before you make your investment decision.

Our common stock is listed on the New York Stock Exchange ("NYSE") under the symbol "DAC." On September 6, 2018, the last reported sale price of our common stock was $1.60 per share, as reported by the NYSE.

Investing in our common stock involves risks that are described in the "Risk Factors" section beginning on page 7 of this prospectus and the "Risk Factors" section of our Annual Report on Form 20-F that is incorporated by reference into this prospectus.

Neither the Securities and Exchange Commission ("SEC") 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 date of this prospectus is , 2018.

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ABOUT THIS PROSPECTUS

This prospectus is part of a resale registration statement on Form F-1 that we have filed with Securities and Exchange Commission (the "**SEC**") pursuant to which the selling stockholders named in this prospectus may, from time to time, offer and sell the common stock covered by this prospectus in one or more offerings. You should not assume that the information contained in this prospectus is accurate on any date subsequent to the date set forth on the front cover of this prospectus or that any information we have incorporated by reference is correct on any date subsequent to the date of the document incorporated by reference, even though this prospectus is delivered or shares of common stock are sold or otherwise disposed of on a later date. It is important for you to read and consider all information contained in this prospectus, including the documents incorporated by reference herein, in making your investment decision. You should also read and consider the information in the documents to which we have referred you under the captions "*Where You Can Find Additional Information*" and *"Incorporation by Reference of Certain Documents"* in this prospectus.

We have not authorized anyone to provide any information or to make any representation other than those contained or incorporated by reference in this prospectus. You must not rely upon any information or representation not contained or incorporated by reference in this prospectus. This prospectus does not constitute an offer to sell or the solicitation of an offer to buy any of our securities other than the common stock covered hereby, nor does this prospectus constitute an offer to sell or the solicitation of an offer to buy any common stock in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction.

This prospectus contains forward-looking statements that are subject to a number of risks and uncertainties, many of which are beyond our control. Please read "*Risk Factors*" and "*Forward-looking Statements; Cautionary Information*."

The selling stockholders named herein acquired the shares of common stock covered by this prospectus in accordance with the terms of the refinancing agreement we entered into with certain of our lenders and our largest stockholder and the transactions contemplated thereby, which we refer to as the "Refinancing". We have entered into a registration rights agreement, as described herein, pursuant to which we agreed to register for resale the common stock beneficially owned by the selling stockholders. See the section of this prospectus entitled "*The Refinancing Transactions*."

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WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form F-1 under the Securities Act relating to this offering of our common stock. This prospectus does not contain all of the information contained in the registration statement. The rules and regulations of the SEC allow us to omit certain information from this prospectus that is included in the registration statement. Statements made in this prospectus concerning the contents of any contract, agreement or other document are summaries of all material information about the documents summarized, but are not complete descriptions of all terms of these documents. If we filed any of these documents as an exhibit to the registration statement, you may read the document itself for a complete description of its terms.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"). In accordance with these requirements, we file reports and other information as a foreign private issuer with the SEC. Those reports or other information may be inspected without charge at the locations described below. As a foreign private issuer, we are exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal stockholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file quarterly reports on Form 10-Q or current reports on Form 8-K with the SEC, or to file our annual report as promptly as U.S. companies whose securities are registered under the Exchange Act. However, we are required to file with the SEC, within four months after the end of each fiscal year, or such applicable time as required by the SEC, an annual report on Form 20-F containing financial statements audited by an independent registered public accounting firm, and will submit to the SEC, on Form 6-K, unaudited quarterly financial information for the first three quarters of each fiscal year.

You may read and copy the registration statement, including the related exhibits and schedules, and any document we file with the SEC without charge at the SEC's public reference room at 100 F Street, N.E., Room 1580, Washington, DC 20549. You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Room 1580, Washington, DC 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. The SEC also maintains an Internet website that contains reports and other information regarding issuers that file electronically with the SEC. Our filings with the SEC are also available to the public through the SEC's website at http://www.sec.gov.

We maintain a corporate website at http://www.danaos.com. Our filings with the SEC, and exhibits incorporated in and amendments to those reports, are available free of charge on our website as soon as reasonably practicable after they are filed with, or furnished to, the SEC. Information contained on, or that can be accessed through, our website does not constitute a part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

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INCORPORATION BY REFERENCE OF CERTAIN DOCUMENTS

The SEC allows us to "incorporate by reference" into this prospectus the information we file with, and furnish to, it, which means that we can disclose important information to you by referring you to those filed documents. We hereby incorporate by reference the documents listed below:

Our Annual Report on Form 20-F for the fiscal year ended December 31, 2017, filed with the SEC on March 7, 2018;

Our Reports on Form 6-K furnished to the SEC on June 25, 2018 (other than Exhibit 99.1 thereto), July 9, 2018, July 11, 2018, and August 14, 2018 (other than Exhibit 99.1 thereto); and

Our Registration Statement on Form 8-A filed with the SEC on October 2, 2006, as amended from time to time.

Any statement contained herein or in a document, all or a portion of which is incorporated or deemed to be incorporated by reference herein, shall be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained herein or in any other subsequently filed document which also is or is deemed to be incorporated by reference herein modifies or supersedes such statement. Any such statement so modified or superseded shall not be deemed, except as so modified or amended, to constitute a part of this prospectus.

Our filings with the SEC, and exhibits incorporated in and amendments to those reports, are available free of charge on our website (http://www.danaos.com) as soon as reasonably practicable after they are filed with, or furnished to, the SEC. Our website and the information contained on that site, or connected to that site, are not incorporated into and are not a part of this prospectus.

Upon written or oral request, we will provide to each person to whom this prospectus is delivered, a copy of any or all of the reports or documents that have been incorporated by reference into this prospectus at no cost. If you would like a copy of any of these documents, at no cost, please write or call us at:

Danaos Corporation
c/o Danaos Shipping Co., Ltd.
14 Akti Kondyli
185 45 Piraeus, Greece
Telephone No.: + 30 210 419 6401
Fax No.: + 30 210 419 6489
Attention: Chief Financial Officer

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FORWARD-LOOKING STATEMENTS; CAUTIONARY INFORMATION

All statements in this prospectus (and in the documents incorporated by reference herein) that are not statements of historical fact are "forward-looking statements" within the meaning of the United States Private Securities Litigation Reform Act of 1995. The disclosure and analysis set forth in this prospectus includes assumptions, expectations, projections, intentions and beliefs about future events in a number of places, particularly in relation to our operations, cash flows, financial position, plans, strategies, business prospects, changes and trends in our business and the markets in which we operate. These statements are intended as "forward-looking statements". In some cases, predictive, future-tense or forward-looking words such as "believe", "intend", "anticipate", "estimate", "project", "forecast", "plan", "potential", "may", "should", "could" and "expect" and similar expressions are intended to identify forward-looking statements, but are not the exclusive means of identifying such statements. In addition, we and our representatives may from time to time make other oral or written statements which are forward-looking statements, including in our periodic reports that we file with the SEC, other information sent to our security holders, and other written materials. We caution that these and other forward- looking statements included in this prospectus (and in the documents incorporated by reference herein) represent our estimates and assumptions as of the date of this prospectus (and as of the date of the documents incorporated by reference herein) or the date on which such oral or written statements are made, as applicable, about factors that are beyond our ability to control or predict, and are not intended to give any assurance as to future results.

Factors that might cause future results to differ include, but are not limited to, the following:

- future operating or financial results;
- pending acquisitions and dispositions, business strategies and expected capital spending;
- operating expenses, availability of crew, number of off-hire days, drydocking requirements and insurance costs;
- general market conditions and shipping market trends, including charter rates, vessel values and factors affecting supply and demand;
- our ability to comply with the terms of the agreements entered into in connection with the Refinancing;
- our financial condition and liquidity, including our ability to comply with covenants in our financing arrangements and to service or refinance our outstanding indebtedness;
- performance by our charterers of their obligations;
- the availability of ships to purchase, the time that it may take to construct new ships, or the useful lives of our ships;
- our ability to obtain financing in the future to fund acquisitions and other general corporate activities;
- our continued ability to enter into multi-year, fixed-rate period charters with our customers;
- our ability to leverage to our advantage our manager's relationships and reputation in the containership shipping sector of the international shipping industry;

changes in governmental rules and regulations or actions taken by regulatory authorities;

potential liability from future litigation; and

other factors discussed in "Risk Factors" in this prospectus.

We undertake no obligation to update or revise any forward-looking statements contained in this prospectus, whether as a result of new information, future events, a change in our views or expectations or otherwise. New factors emerge from time to time, and it is not possible for us to predict all of these factors. Further, we cannot assess the impact of each such factor on our business or the extent to which any factor, or combination of factors, may cause actual results to be materially different from those contained in any forward-looking statement.

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PROSPECTUS SUMMARY

This summary highlights information contained in other parts of and incorporated by reference into this prospectus. Because it is only a summary, it does not contain all of the information that you should consider before investing in our common stock and it is qualified in its entirety by, and should be read in conjunction with, the more detailed information appearing elsewhere in and incorporated by reference into this prospectus. You should read the entire prospectus carefully, and all documents incorporated by reference into this prospectus, including "Risk Factors" and our financial statements and the related notes, before deciding to buy our common stock.

Our Company

We are an international owner of containerships, chartering our vessels to many of the world's largest liner companies. As of August 31, 2018, we had a fleet of 55 containerships aggregating 327,616 TEUs, making us among the largest containership charter owners in the world, based on total TEU capacity. Gemini Shipholdings Corporation ("**Gemini**"), in which we have a 49% minority equity interest, had a fleet of four containerships of 23,998 TEU aggregate capacity as of August 31, 2018.

Our strategy is to charter our containerships principally under multi-year, fixed-rate period charters to a diverse group of liner companies, including many of the largest companies globally, as measured by TEU capacity. As of August 31, 2018, these customers included CMA-CGM, Yang Ming, COSCO, Hyundai Merchant Marine, ZIM Israel Integrated Shipping Services, Hapag Lloyd, Maersk, Evergreen, MSC, Ocean Network Express and KMTC; and for Gemini, NYK, Hapag Lloyd, TS Lines and SM Lines.

Our Fleet

We deploy our containership fleet principally under multi-year charters with major liner companies that operate regularly scheduled routes between large commercial ports, although in weaker containership charter markets such as is currently prevailing we charter more of our vessels on shorter term charters so as to be available to take advantage of any increase in charter rates. As of August 31, 2018, our containership fleet was comprised of fifty-one containerships deployed on time charters, fourteen of which are scheduled to expire in 2018, and four containerships deployed on bareboat charters. The average age (weighted by TEU) of the 55 vessels in our containership fleet was approximately 9.9 years as of August 31, 2018. As of March 31, 2018, the average remaining duration of the charters for our containership fleet was 5.4 years (weighted by aggregate contracted charter hire).

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The table below provides additional information, as of August 31, 2018, about our fleet of 55 cellular containerships and the four cellular containerships owned by Gemini, in which we have a 49% equity interest.

Vessel Name	Year Built	Vessel Size (TEU)	Initial Time Charter Term(1)	Expiration of Charter(1)	Charterer
MSC Ambition (ex Hyundai Ambition)	2012	13,100	12 years	June 2024	Hyundai
Maersk Exeter (ex Hyundai Speed)	2012	13,100	12 years	June 2024	Hyundai
Maersk Enping (ex Hyundai Smart)	2012	13,100	12 years	May 2024	Hyundai
Hyundai Respect (ex Hyundai Tenacity)(2)(5)	2012	13,100	12 years	March 2024	Hyundai
Hyundai Honour (ex Hyundai Together)(2)(5)	2012	13,100	12 years	February 2024	Hyundai
Express Rome	2011	10,100	1 year	January 2019	Hapag Lloyd
Express Berlin	2011	10,100	2 years	September 2019	Yang Ming
Express Athens	2011	10,100	1 year	January 2019	Hapag Lloyd
CSCL Le Havre	2006	9,580	12 years	September 2018	COSCO
CSCL Pusan	2006	9,580	0.2 year	October 2018	CMA-CGM
CMA CGM Melisande	2012	8,530	12 years	November 2023	CMA-CGM
CMA CGM Attila	2011	8,530	12 years	April 2023	CMA-CGM
CMA CGM Tancredi	2011	8,530	12 years	May 2023	CMA-CGM
CMA CGM Bianca	2011	8,530	12 years	July 2023	CMA-CGM
CMA CGM Samson	2011	8,530	12 years	September 2023	CMA-CGM
CSCL America	2004	8,468	1.0 year	June 2019	ZIM
Europe	2004	8,468	0.8 year	January 2019	COSCO
CMA CGM Moliere	2009	6,500	12 years	August 2021	CMA-CGM
CMA CGM Musset	2010	6,500	12 years	February 2022	CMA-CGM
CMA CGM Nerval	2010	6,500	12 years	April 2022	CMA-CGM
CMA CGM Rabelais	2010	6,500	12 years	June 2022	CMA-CGM
CMA CGM Racine	2010	6,500	12 years	July 2022	CMA-CGM
Priority	2002	6,402	0.2 year	August 2018	ONE
Performance	2002	6,402	1 year	May 2019	CMA-CGM
YM Seattle	2007	4,253	12 years	July 2019	Yang Ming
YM Vancouver	2007	4,253	12 years	September 2019	Yang Ming
ZIM Rio Grande	2008	4,253	12 years	May 2020	ZIM
ZIM Sao Paolo	2008	4,253	12 years	August 2020	ZIM
ZIM Kingston (ex OOCL Istanbul)	2008	4,253	12 years	September 2020	ZIM
ZIM Monaco	2009	4,253	12 years	November 2020	ZIM
ZIM Dalian (ex OOCL Novorossiysk)	2009	4,253	12 years	February 2021	ZIM
ZIM Luanda	2009	4,253	12 years	May 2021	ZIM
Derby D	2004	4,253	0.9 year	March 2019	CMA-CGM
ANL Tongala (ex Deva)	2004	4,253	0.9 year	March 2019	CMA-CGM
Dimitris C	2001	3,430	1.0 year	June 2019	CMA-CGM
Express Black Sea	2011	3,400	0.5 year	November 2018	KMTC
Express Spain	2011	3,400	1 year	November 2018	Maersk
Express Argentina	2010	3,400	0.5 year	May 2019	Maersk
Express Brazil	2010	3,400	1 year	July 2019	CMA-CGM
Express France	2010	3,400	1 year	October 2018	CMA-CGM
Singapore (ex YM Singapore)	2004	3,314	12 years	October 2019	Yang Ming
Colombo	2004	3,314	12 years	March 2019	Yang Ming
Danae C	2001	2,524	2 years	January 2020	Hapag Lloyd
MSC Zebra	2001	2,602	2 years	August 2020	MSC
Amalia C	1998	2,452	2 years	August 2019	Yang Ming
Advance (ex Hyundai Advance)	1997	2,200	0.4 year	December 2018	Evergreen

Future (ex Hyundai Future)	1997	2,200	0.3 year	November 2018	Maersk
Sprinter (ex Hyundai Sprinter)	1997	2,200	0.5 year	October 2018	Evergreen
Stride (ex Hyundai Stride)	1997	2,200	0.5 year	September 2018	Maersk
Progress C (ex Hyundai Progress)	1998	2,200	0.4 year	October 2018	Evergreen
Bridge (ex Hyundai Bridge)	1998	2,200	0.2 year	November 2018	Maersk
Highway (ex Hyundai Highway)	1998	2,200	0.2 year	November 2018	COSCO
Vladivostok (ex Hyundai Vladivostok)	1997	2,200	0.5 year	September 2018	Maersk

			Gemini Vessels		
Lodestar (ex NYK Lodestar)(3)	2001	6,422	0.5 year	September 2018	TS Lines
NYK Leo(3)	2002	6,422	3 years	February 2019	NYK
Suez Canal(3)(4)	2002	5,610	0.5 year	November 2018	SM Lines
Genoa(3)(4)	2002	5,544	0.8 year	July 2019	Hapag Lloyd

			Bareboat Charter Term(1)		
YM Mandate	2010	6,500	18 years	January 2028	Yang Ming
YM Maturity	2010	6,500	18 years	April 2028	Yang Ming

(1) Earliest date charters could expire. Most charters include options for the charterers to extend their terms.

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(2) Vessels' time charters were changed to bareboat charters from May 2017 to May 2020.

(3) Vessels acquired by Gemini, in which Danaos holds a 49% equity interest.

(4) A subsidiary of Gemini holds a leasehold bareboat charter interest in such vessel, which was financed by and is subject to a capital lease pursuant to which such subsidiary will acquire all rights to such vessel at the end of such lease.

(5) In connection with the Refinancing, as defined below, we have undertaken to seek to sell the *Hyundai Honour* and the *Hyundai Respect*, with the net proceeds from such sales to be applied pro rata to repay the new credit facilities secured by mortgages on such vessels.

Recent Developments

Debt Refinancing

We consummated our debt refinancing (the "Refinancing") with certain of our lenders on August 10, 2018 (the "Closing Date"). The Refinancing involved our entry into modified or amended and restated credit facilities, reflecting a $551 million reduction in our debt, reset financial and certain other covenants, modified interest rates and amortization profiles and extended debt maturities by approximately five years to December 31, 2023 (or, in some cases, June 30, 2024). In the Refinancing, we issued to certain of our lenders an aggregate of 99,342,271 shares of our common stock on the Closing Date, representing 47.5% of our issued and outstanding common stock after giving effect to such issuance. These shares are being registered for resale, from time to time, pursuant to the registration statement of which this prospectus forms a part. Please read the section of this prospectus entitled *"The Refinancing Transactions"* as well as our Reports on Form 6-K furnished to the SEC on June 25, 2018 and August 14, 2018.

Preliminary Financial Results for the Three Months Ended March 31, 2018

On June 26, 2018, we issued a press release containing our preliminary financial results for the three months ended March 31, 2018 and 2017. Please refer to our Report on Form 6-K furnished to the SEC on July 9, 2018.

The preliminary financial results for the three months ended March 31, 2018 and 2017 incorporated by reference into this prospectus has been prepared by, and is the responsibility of, the Company's management. PricewaterhouseCoopers S.A. has not audited, reviewed, compiled, or applied agreed-upon procedures with respect to the preliminary financial data. Accordingly, PricewaterhouseCoopers S.A. does not express an opinion or any other form of assurance with respect thereto.

Our Corporate Information

Danaos Corporation, formerly Danaos Holdings Limited, was formed on December 7, 1998 under the laws of Liberia. We operate through a number of wholly-owned subsidiaries which own the vessels in our fleet. Danaos Holdings Limited was redomiciled in the Marshall Islands on October 7, 2005. In connection with the redomiciliation, the Company changed its name to Danaos Corporation. Our principal executive offices are c/o Danaos Shipping Co. Ltd., Athens Branch, 14 Akti Kondyli, 185 45 Piraeus, Greece. Our telephone number at that address is +30 210 419 6480. Our website is http://www.danaos.com. Information contained on, or that can be accessed through, our website does not constitute a part of this prospectus and is not incorporated by reference herein. We have included our website address in this prospectus solely as an inactive textual reference.

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THE OFFERING

Issuer	Danaos Corporation, a Marshall Islands corporation.
Common stock offered by the selling stockholders	99,342,271 shares of common stock
Common stock issued and outstanding	209,141,623 shares of common stock(1)
Selling stockholders	The selling stockholders are certain of our lenders which were issued shares of common stock in connection with the consummation of the Refinancing. See "*Principal and Selling Stockholders*" for further discussion.
Determination of offering price	The selling stockholders may sell all or some of the shares of our common stock offered hereby from time to time at those prices as they may determine at the time of sale, as more fully described under the heading "*Plan of Distribution*."
Use of proceeds	The selling stockholders will receive all of the proceeds from the sale of any common stock sold by them pursuant to this prospectus. We will not receive any proceeds from the sale of any common stock by the selling stockholders. See "*Use of Proceeds*."
Risk factors	See "*Risk Factors*" included elsewhere in this prospectus for a discussion of factors you should carefully consider before deciding to invest in our common stock.

(1) Based on 209,141,623 shares of common stock outstanding on August 31, 2018, including 99,342,271 shares of common stock issued in connection with the Refinancing.

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SELECTED CONSOLIDATED FINANCIAL DATA

The following table presents selected consolidated financial and other data of Danaos Corporation and its consolidated subsidiaries for each of the years in the five-year period ended December 31, 2017. The table should be read together with Item 5. "*Operating and Financial Review and Prospects*" contained in our Annual Report on Form 20-F for the year ended December 31, 2017. The selected consolidated financial data of Danaos Corporation as of December 31, 2017 and 2016 and each of the three years ended December 31, 2017 is derived from our consolidated financial statements and notes thereto included in our Annual Report on Form 20-F for the year ended December 31, 2017, which have been prepared in accordance with U.S. generally accepted accounting principles, or "U.S. GAAP", and have been audited by PricewaterhouseCoopers S.A., an independent registered public accounting firm. Our selected consolidated financial data as of December 31, 2015, 2014 and 2013 and for each of the two years ended December 31, 2014 is derived from our consolidated financial statements not included or incorporated by reference herein and reflect the retrospective application of the change in accounting principle for deferred finance costs.

Our audited consolidated statements of operations, comprehensive income, changes in stockholders' equity and cash flows for the years ended December 31, 2017, 2016 and 2015, and the consolidated balance sheets at December 31, 2017 and 2016, together with the notes thereto, are

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included in "*Financial Statements*" contained in our Annual Report on Form 20-F for the year ended December 31, 2017 incorporated by reference herein and should be read in their entirety.

	Year Ended December 31,				
	2017	**2016**	**2015**	**2014**	**2013**
	In thousands, except per share amounts and other data				
STATEMENT OF OPERATIONS					
Operating revenues	$ 451,731	$ 498,332	$ 567,936	$ 552,091	$ 588,117
Voyage expenses	(12,587)	(13,925)	(12,284)	(12,974)	(11,770)
Vessel operating expenses	(106,999)	(109,384)	(112,736)	(113,755)	(122,074)
Depreciation	(115,228)	(129,045)	(131,783)	(137,061)	(137,414)
Amortization of deferred drydocking and special survey costs	(6,748)	(5,528)	(3,845)	(4,387)	(5,482)
Impairment loss		(415,118)	(41,080)	(75,776)	(19,004)
Bad debt expense		(15,834)			
General and administrative expenses	(22,672)	(22,105)	(21,831)	(21,442)	(19,458)
Gain/(loss) on sale of vessels		(36)		5,709	(449)
Income/(loss) from operations	187,497	(212,643)	244,377	192,405	272,466
Interest income	5,576	4,682	3,419	1,703	2,210
Interest expense(1)	(86,556)	(82,966)	(84,435)	(95,050)	(106,616)
Other finance expenses(1)	(4,126)	(4,932)	(4,658)	(4,687)	(4,689)
Equity income/(loss) on investments	965	(16,252)	(1,941)		
Other income/(expenses), net	(15,757)	(41,602)	111	422	302
Unrealized and realized losses on derivatives	(3,694)	(12,482)	(39,857)	(98,713)	(126,150)
Total other expenses, net	(103,592)	(153,552)	(127,361)	(196,325)	(234,943)
Net income/(loss)	$ 83,905	$ (366,195)	$ 117,016	$ (3,920)	$ 37,523
PER SHARE DATA					
Basic and diluted earnings/(loss) per share of common stock	$ 0.76	$ (3.34)	$ 1.07	$ (0.04)	$ 0.34
Basic and diluted weighted average number of shares (in thousands)	109,824	109,802	109,785	109,676	109,654
CASH FLOW DATA(2)					
Net cash provided by operating activities	$ 181,073	$ 261,967	$ 271,676	$ 192,181	$ 189,025
Net cash provided by/(used in) investing activities	1,758	(9,379)	(13,292)	11,437	6,087
Net cash provided by/(used in) financing activities	(189,653)	(251,124)	(243,861)	(214,041)	(182,587)
Net increase/(decrease) in cash and cash equivalents	(6,822)	1,464	14,523	(10,423)	12,525
BALANCE SHEET DATA (at year end)					
Total current assets	$ 125,999	$ 135,954	$ 127,570	$ 103,073	$ 126,866
Total assets(1)	2,986,396	3,127,064	3,662,121	3,802,172	4,002,644
Total current liabilities, including current portion of long-term debt	2,379,839	2,566,281	312,145	328,082	369,888
Current portion of long-term debt	2,329,601	2,504,932	269,979	178,116	146,462
Current portion of Vendor financing				46,530	57,388
Long-term debt, net of current portion(1)			2,470,417	2,723,984	2,901,733
Vendor financing, net of current portion				17,837	64,367
Total stockholders' equity	548,705	487,713	841,914	688,149	598,476
common stock shares outstanding (in thousands)	109,799	109,799	109,782	109,669	109,653
common stock at par value	1,098	1,098	1,098	1,097	1,097
OTHER DATA					
Number of vessels at period end	55	55	56	56	59
TEU capacity at period end	327,616	329,588	334,239	334,239	345,179
Ownership days	20,075	20,138	20,440	20,406	22,257
Operating days	19,345	19,057	20,239	19,905	20,784

(1) The comparative figures presented give effect to a retrospective application of the change in accounting principle for deferred finance costs as per Accounting Standards Update No. 2015-03 "Simplifying the Presentation of Debt Issuance Costs" ("ASU 2015-03"), which resulted in a reduction of deferred charges, total assets, long-term debt, net and total liabilities by $49,020 and $63,908 as of December 31, 2014 and 2013, respectively and the

reclassification of the amortization of deferred finance costs from "Other finance expenses" to "Interest expense" of $15,431 for the year ended December 31, 2013.

(2) Our cash flow data for the periods presented has not yet been recast for our adoption, effective as of January 1, 2018, of Accounting Standards Updates 2016-15 and 2016-18.

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RISK FACTORS

You should consider carefully all of the information set forth in this prospectus and the documents incorporated by reference herein, unless expressly provided otherwise, and, in particular, the risk factors described in "Risk Factors" contained in our Annual Report on Form 20-F for the year ended December 31, 2017, incorporated herein by reference. Set forth below are risks related to the Refinancing and our new credit facilities that we entered into in connection with the Refinancing, as well as risks related to our common stock and tax considerations, which update the risk factors related to these matters contained in our Annual Report on Form 20-F for the year ended December 31, 2017 which also contains a discussion of other risks related to our company, our business and our industry. The risks described below and in any document incorporated by reference are not the only ones we face, but are those we currently consider to be material. There may be other unknown or unpredictable economic, business, competitive, regulatory or other factors that could have material adverse effects on our future results. If that occurs, the price of our common stock could decline materially and you could lose all or part of your investment. Past financial performance may not be a reliable indicator of future performance and historical trends should not be used to anticipate results or trends in future periods.

Risks Relating to our New Credit Facilities

Our new credit facilities contain covenants and other provisions imposing operating and financial restrictions on us.

Our new credit facilities impose various operating and financial restrictions on us. These restrictions generally preclude us from:

creating liens on our assets, generally, unless for the equitable and ratable benefit of our existing lenders;

selling capital stock of our subsidiaries;

ordering newbuilding vessels unless the financing used for such purpose does not result in a decrease of the applicable minimum charter attached collateral coverage;

incurring new debt financing secured by vessels within the existing fleet, unless the existing debt secured thereby is repaid in full;

disposing of assets without the consent of the lenders that have loans collateralized by such assets and, in case of such approval, using the proceeds thereof for purposes other than to repay indebtedness;

using more than a limited amount of our free cash from operations for purposes other than repayment of indebtedness;

engaging in transactions that would constitute a change of control, as defined in our new credit facilities, without repaying all of our indebtedness in full;

paying dividends or repurchasing stock prior to our satisfaction of certain conditions and subject to our compliance with our credit facility covenants; or

changing our manager or certain members of our management.

As a result, we may have reduced discretion in operating our business and may have difficulty growing our business.

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Containership charter rates and vessel values may affect our ability to comply with various financial and collateral covenants in our new credit facilities.

Our new credit facilities, which are secured by, among other things, mortgages on our vessels, require us to maintain specified collateral coverage ratios and satisfy financial covenants. Low containership charter rates, or the failure of our charterers to fulfill their obligations under their charters for our vessels, due to financial pressure on these liner companies from weak demand for the seaborne transport of containerized cargo or otherwise, may adversely affect our ability to comply with these covenants. The market value of containerships is sensitive to, among other things, changes in the charter markets with vessel values deteriorating in times when charter rates are falling and improving when charter rates are anticipated to rise. As a result of depressed containership market conditions, and the cancellation of eight of our charters by Hanjin Shipping in conjunction with its filing for bankruptcy court protection, we were in breach of the financial covenants in our prior financing arrangements that were refinanced and replaced by our new credit facilities.

Our new credit facilities contain financial covenants set at levels with which we will be initially in compliance and that require us to maintain: (i) minimum collateral to loan value coverage on a charter-free basis increasing from 57.0% as of December 31, 2018 to 100% as of September 30, 2023 and thereafter, (ii) minimum collateral to loan value coverage on a charter-attached basis increasing from 69.5% as of December 31, 2018 to 100% as of September 30, 2023 and thereafter, (iii) minimum liquidity of $30 million throughout the term of the new credit facilities, (iv) maximum consolidated net leverage ratio, declining from 7.50x as of December 31, 2018 to 5.50x as of September 30, 2023 and thereafter, (v) minimum interest coverage ratio of 2.50x throughout the term of the new credit facilities and (vi) minimum consolidated market value adjusted net worth increasing from negative $510 million as of December 31, 2018 to $60 million as of September 30, 2023 and thereafter. We also amended the terms of our Sinosure-CEXIM credit facility in connection with the Refinancing to align the covenants contained therein with the covenants for our other facilities described in this paragraph.

If we are unable to meet our covenant compliance obligations under our new credit facilities, and are unable to reach an agreement with our lenders to obtain compliance waivers, our lenders could then accelerate our indebtedness and foreclose on the vessels in our fleet securing those credit facilities. Any such default could result in cross-defaults under our other credit facilities, and the consequent acceleration of the indebtedness thereunder and the commencement of similar foreclosure proceedings by other lenders. The loss of any of our vessels would have a material adverse effect on our operating results and financial condition and could impair our ability to operate our business.

Substantial debt levels could limit our flexibility to obtain additional financing and pursue other business opportunities and our ability to service our outstanding indebtedness will depend on our future operating performance, including the charter rates we receive under charters for our vessels.

We have aggregate principal amount of indebtedness outstanding of approximately $1.7 billion, reflecting the $551 million reduction in our indebtedness in connection with the Refinancing. We may seek to incur substantial additional indebtedness, as market conditions warrant, to grow our fleet to the extent that we are able to obtain such financing and our credit facilities permit such financing. This level of debt could have important consequences to us, including the following:

- our ability to obtain additional financing, if necessary, for working capital, capital expenditures, acquisitions or other purposes may be impaired or such financing may be unavailable on favorable terms;

- we will need to use a substantial portion of our free cash from operations, as required under the terms of our new credit facilities, to make principal and interest payments on our debt, reducing the funds that would otherwise be available for future business opportunities and, if permitted

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by our new credit facilities and reinstated by our board of directors, dividends to our stockholders;

our debt level could make us more vulnerable than our competitors with less debt to competitive pressures or a downturn in our business or the economy generally; and

our debt level may limit our flexibility in responding to changing business and economic conditions.

Our ability to service our debt will depend upon, among other things, our future financial and operating performance, which will be affected by prevailing economic conditions and financial, business, regulatory and other factors, some of which are beyond our control. In particular, the charter rates we obtain for our vessels, including our vessels on shorter term time charters or other charters expiring in the near future, will have a significant impact on our ability to service our indebtedness. If we do not generate sufficient cash flow to service our debt, we may be forced to take actions such as reducing or delaying our business activities, acquisitions, investments or capital expenditures, selling assets, refinancing our debt or seeking additional equity capital. We may not be able to effect any of these remedies on satisfactory terms, or at all.

In addition, we do not have any additional amounts available for borrowing under our credit facilities. Accordingly, we are dependent on our cash flows from operations to meet our operating expenses and debt service obligations. If we need additional liquidity and are unable to obtain such liquidity from existing or new lenders or in the capital markets, such as the common stock offering for net proceeds of at least $50 million that we have agreed to seek to complete within 18 months of the consummation of the Refinancing, or if our new credit facilities do not permit additional debt that we require (and we are unable to obtain waivers from required lenders), we may be unable to meet our liquidity obligations which could lead to a default under our credit facilities.

We cannot guarantee that we will be able to realize the anticipated benefits from the Refinancing. If we are unable to meet our obligations, we would need to reach another arrangement with our creditors, which may be on terms that are less favorable to us than those of the transactions entered into in connection with the Refinancing. Notwithstanding the Refinancing, we remain significantly leveraged and continue to face risks associated with a highly leveraged company.

Risks Relating to Our Common Stock

/TD> Ended June 30, Ended June 30, 2014 2015 2014 2015 (In thousands, except share and per share amounts) (In thousands, except share and per share amounts)

Historical net income (loss) per share

Numerator: Net income (loss) attributable to common stockholders $33,470 $(47,894) $(212,559) $(87,280)Denominator: Weighted average shares used in calculating net loss per share - basic 20,965,094 24,014,092 20,238,955 23,100,222 Dilutive effect of equity incentive plans' shares 1,239,840 - - -

Weighted average shares used in calculating net income (loss) per share - basic and diluted

22,204,934 24,014,092 20,238,955 23,100,222 Net income/(loss) per share: Basic $1.60 $(1.99) $(10.50) $(3.78)Diluted $1.51 $(1.99) $(10.50) $(3.78)

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2015	2014	2015
	(In thousands)		(In thousands)	
Options	182	1,232	1,455	1,232
Restricted stock units	-	37,158	84	37,158
Total	182	38,390	1,539	38,390

10. Litigation

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

The lawsuits allege that the Company made material misrepresentations and/or omissions of material fact in its public disclosures during the period from January 9, 2014 to January 10, 2014, in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder. The alleged improper disclosures relate to the Company's January 9, 2014 announcement that the FLINT trial had been stopped early based on a pre-defined interim efficacy analysis. Specifically, the lawsuits claim that the January 9, 2014 announcement was misleading because it did not contain information regarding certain lipid abnormalities seen in the FLINT trial in OCA-treated patients compared to placebo. On April 22, 2014, two individuals each moved to consolidate the cases and a lead plaintiff was subsequently appointed by the Court. On June 27, 2014, the lead plaintiff filed an amended complaint on behalf of the putative class as contemplated by the order of the Court. On August 14, 2014, the defendants filed a motion to dismiss the complaint. Oral arguments on the motion to dismiss were held on February 24, 2015. On March 4, 2015, the defendants' motion to dismiss was denied by the Court. The defendants answered the amended complaint on April 13, 2015. The parties are currently undergoing discovery in relation to this matter.

The lead plaintiff seeks unspecified monetary damages on behalf of the putative class and an award of costs and expenses, including attorneys' fees.

The Company believes that it has valid defenses to the claims in the lawsuit and intends to deny liability and defend itself vigorously. There can be no assurance, however, that the Company will be successful. At this time, no assessment can be made as to the likely outcome of this action or whether the outcome will be material to the Company. Therefore, the Company has not accrued for any loss contingencies related to this lawsuit.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read together with our unaudited financial statements and the notes to those financial statements appearing elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto and management's discussion and analysis of financial condition and results of operations for the year ended December 31, 2014 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 2, 2015. This discussion contains forward-looking statements that involve significant risks and uncertainties. As a result of many factors, such as those set forth in Item 1.A. "Risk Factors" of our Annual Report on Form 10-K and this Quarterly Report on Form 10-Q and any updates to those risk factors contained in our subsequent periodic and current reports filed with the Securities and Exchange Commission, our actual results may differ materially from those anticipated in these forward-looking statements.

Overview

We are a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat chronic liver diseases. 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, selectively binds to and activates the farnesoid X receptor, or FXR, which we believe has broad liver-protective properties. OCA has been tested in five placebo-controlled clinical trials, including a Phase 3 clinical trial in patients with primary biliary cirrhosis, or PBC, and two Phase 2 clinical trials in patients with nonalcoholic fatty liver disease, or NAFLD, and nonalcoholic steatohepatitis, or NASH. OCA met the primary efficacy endpoint in each of these trials with statistical significance.

In January 2015, OCA received breakthrough therapy designation from the U.S. Food and Drug Administration, or FDA, for the treatment of NASH patients with liver fibrosis. OCA has also been granted fast track designation by the FDA for the treatment of patients with PBC who have an inadequate response to or are intolerant of ursodiol. OCA has received orphan drug designation in the United States and the European Union for the treatment of PBC and primary sclerosing cholangitis, or PSC.

Our most advanced development program for OCA is for PBC as a second line treatment for patients who have an inadequate response to the current standard of care or as monotherapy for those who are unable to tolerate standard of care therapy and therefore need additional treatment. PBC is a chronic autoimmune liver disease that, if inadequately treated, may eventually lead to cirrhosis, liver failure and death. In March 2014, we completed a Phase 3 clinical trial, known as the POISE trial, in which OCA achieved the primary endpoint for the treatment of PBC. We intend to use

these results, along with two previously completed randomized Phase 2 clinical trials of OCA in PBC, as the basis for seeking the first regulatory approvals to market OCA in the United States, Europe, Canada and Australia. In June 2015, we completed our filings for marketing approval of OCA in PBC in the United States under the FDA's accelerated approval pathway and Europe in June 2015. We also plan to apply for marketing approval of OCA in PBC in other markets such as Canada and Australia. If we receive marketing approval from regulatory authorities, we plan to initiate the commercial launch of OCA in PBC in the United States, certain European countries and Canada in 2016.

OCA achieved the primary endpoint in a Phase 2b clinical trial for the treatment of NASH, known as the FLINT trial, which was sponsored by the U.S. National Institute of Diabetes and Digestive and Kidney Diseases, or NIDDK, a part of the National Institutes of Health. The FLINT trial was completed in July 2014. We finalized the design of our Phase 3 clinical program in non-cirrhotic NASH patients with liver fibrosis, known as the REGENERATE trial, during the second quarter of 2015, following the completion of our regulatory discussions with the FDA and the European Medicines Agency, or EMA, and plan to initiate the clinical program in the third quarter of 2015. We also intend to initiate a clinical trial in 2015 characterizing the lipid metabolic effects of OCA and cholesterol management effects of concomitant statin administration in NASH patients. Our collaborator, Sumitomo Dainippon Pharma Co. Ltd., or Sumitomo Dainippon, has completed enrollment in a 200- patient Phase 2 NASH clinical trial of OCA in Japan with a primary efficacy endpoint similar to that used in our Phase 2b FLINT trial, which is anticipated to be completed by the end of 2015.

Our net income for the three months ended June 30, 2014 was approximately $33.5 million while our net loss for the three months ended June 30, 2015 was approximately $47.7 million. Our net losses for the six months ended June 30, 2014 and 2015 were $212.6 million and $87.0 million, respectively. As of June 30, 2015, we had an accumulated deficit of approximately $556.2 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 and, for the six months ended June 30, 2014, from the mark-to-market of our previously outstanding liability-classified warrants. Our net income for the three months ended June 30, 2014 is primarily attributable to the revaluation of our warrants.

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

- complete the development of our lead product candidate, OCA, for the treatment of PBC, and continue the development of OCA in NASH and other patient populations;
- seek to obtain regulatory approvals for OCA for PBC, NASH and other potential patient populations;
- prepare for the potential commercialization of OCA in PBC, including establishing our sales, marketing and distribution capabilities and increasing our drug manufacturing activities;
- continue development of our other product candidates, such as INT-767, and engage in other research and development activities;

- maintain, expand and protect our intellectual property portfolio;
- increase our product development, scientific, commercial and administrative personnel and expand our facilities and operations in the United States and abroad; 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 is subject to significant uncertainty. Accordingly, we anticipate that we will need to raise additional capital to commercialize OCA on a worldwide basis and continue our research and development activities in relation to OCA and our other pipeline candidates. Until such time, if ever, as we can generate substantial revenue from product sales, we expect to finance our operating activities through a combination of equity offerings, debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop our product candidates.

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

Financial Overview

Revenue

To date, we have not generated any revenue from the sale of products. All of our revenue has been derived from our collaborative agreements for the development and commercialization of certain of our product candidates. We have entered into an exclusive licensing agreement with Sumitomo Dainippon for the development of OCA in Japan, China and Korea. Under the terms of the agreement, we have received up-front payments of $16.0 million, including $1.0 million upon the exercise by Sumitomo Dainippon of its option to add Korea to its licensed territories, and may be eligible to receive up to approximately $300 million in additional payments for development, regulatory and commercial sales milestones for OCA in the licensed territories. As of June 30, 2015, we have achieved $1.0 million of the development milestones.

For accounting purposes, the up-front payments are recorded as deferred revenue and amortized over time and milestone payments are recognized once earned. We recognized $851,000 and $1.9 million in license revenue for the six months ended June 30, 2014 and 2015, respectively. All of the revenue recognized in the six months ended June

30, 2014 related to the amortization of the up-front payments under the collaboration agreement. For the six months ended June 30, 2015, $891,000 resulted from the amortization of the up-front payments under the collaboration agreement and $1.0 million resulted from the milestone achieved in the period. We anticipate that we will recognize revenue of approximately $1.8 million per year through 2020, for the amortization of the relevant up-front collaboration payments from Sumitomo Dainippon. In the future, we may generate revenue from a combination of license fees and other up-front payments, research and development payments, milestone payments, product sales and royalties in connection with our collaborations. We expect that any revenue we generate will fluctuate from quarter-to-quarter as a result of the timing of our achievement of preclinical, clinical, regulatory and commercialization milestones, if at all, the timing and amount of payments relating to such milestones and the extent to which any of our products are approved and successfully commercialized by us or our collaboration partners. If our collaboration partners fail to develop product candidates in a timely manner or obtain regulatory approval for them, our ability to generate future revenues, and our results of operations and financial position would be adversely affected.

Research and Development Expenses

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

Direct costs:

- 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 activities associated with acquiring and manufacturing OCA;
- costs associated with discovery and early stage research initiatives; and
- costs related to compliance with regulatory requirements.

Personnel costs:

·salaries and related benefit expenses for personnel in research and development functions; and
·costs related to stock compensation granted to personnel in research and development functions.

Indirect costs:

·rent and other facilities-related costs; and
·product-related legal costs.

We plan to increase our research and development expenses for the foreseeable future as we continue the development of OCA for the treatment of PBC, NASH and PSC and other indications and to further advance the development of our other product candidates, subject to the availability of additional funding.

The table below summarizes our direct research and development expenses by program for the periods indicated. We do not allocate personnel costs and indirect costs related to our research and development function to specific product candidates. Those expenses are included in personnel costs and indirect research and development expense in the table below.

	Six Months Ended June 30,	
	2014	2015
	(In thousands)	
Direct research and development expense by program:		
OCA	$14,924	$22,015
Research and discovery initiatives	–	4,704
INT-767	869	3,192
Total direct research and development expense	15,793	29,911
Personnel costs (1)	12,023	22,621
Indirect research and development expense	1,396	3,728
Total research and development expense	$29,212	$56,260

(1) Personnel costs include stock-based compensation expense associated with stock options and restricted stock awards granted to employees and non-employees of $7.4 million and $10.1 million for the six months ended June 30, 2014 and 2015, respectively.

For the six months ended June 30, 2015, we had a net increase of 22 research and development personnel in support of our expansion in activities.

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

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

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

OCA

The majority of our research and development resources were focused on completing our NDA and Marketing Authorization Application, or MAA, filings for OCA for the treatment of PBC, which were completed during June 2015. In addition, we have incurred and expect to continue to incur significant expenses in connection with these efforts, including:

- completing our POISE trial of OCA in patients with PBC in March 2014 and continuing the long-term safety extension phase of the trial potentially through 2019.
- initiating our clinical outcomes confirmatory trial for OCA in PBC in December 2014 and continuing the trial on a post-marketing basis.
- conducting numerous Phase 1 clinical trials during 2014 in support of the NDA and MAA filings for OCA in PBC.
- contracting with third-party manufacturers to produce the quantities of OCA needed for regulatory approval as well as the necessary supplies for our other contemplated trials and working to secure second manufacturers as part of our strategy to secure more than one approved supplier of OCA in the future. We are building commercial supplies, including supplies of the starting material for manufacturing OCA.
- contracting with and planning to engage a number of consultants and other third party vendors in relation to our seeking of regulatory approval and implementing various electronic software and systems in relation to our regulatory activities.

In addition, we are evaluating OCA in other chronic liver diseases, particularly NASH and PSC. We completed regulatory discussions regarding the Phase 3 trial design for our clinical program for OCA in non-cirrhotic NASH patients with liver fibrosis in June 2015 and plan to initiate the trial in the third quarter of 2015. We are also planning a clinical trial characterizing lipid metabolic effects of OCA and cholesterol management effects of concomitant statin administration in NASH patients. For PSC, we initiated a Phase 2 clinical trial in December 2014. As a result, we expect that our expenditures in connection with our NASH and PSC programs will increase significantly in future periods.

INT-767 and INT-777

We intend to continue to develop INT-767 (a dual FXR/TGR5 agonist) and INT-777 (a selective TGR5 agonist). Currently, we plan to continue with preclinical development of INT-767 through to the filing of an Investigational New Drug, or IND, application and, subject to the IND application becoming effective, plan to initiate a Phase 1 trial of INT-767 in healthy volunteers around year end 2015. We also intend to conduct additional preclinical work on INT-777 to further characterize its therapeutic potential.

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

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for employees in executive and operational functions, including sales and marketing, finance, information technology, legal and human resources. Other significant general and administrative expenses include non-cash stock-based compensation expenses, expenses related to our OCA pre-commercialization activities, facilities costs, accounting and legal services, information technology and other expenses of operating as a public company.

Our general and administrative expenses have increased and will continue to increase as we operate as a public company and due to the potential commercialization of our product candidates. We further plan on expanding our operations both in the United States, Europe and other countries such as Canada and Australia, which will increase our general and administration expenses. We believe that these activities will result in increased costs related to the hiring of significant additional personnel, increased fees for outside consultants, lawyers and accountants and the addition of facilities. We have also incurred and will continue to incur increased costs to comply with corporate governance, internal controls, compliance and similar requirements applicable to public companies with expanding operations and biopharmaceutical companies seeking to commercialize its product candidates. For the six months ended June 30, 2015, we had a net increase of 47 corporate and commercial personnel in support of our expansion in activities.

Other Income, Net

Other income, net consists of interest income earned on our cash, cash equivalents and investment securities, offset by management fees, as well as capital base, franchise and real estate taxes.

Revaluation of Warrants

In conjunction with various financing transactions prior to our initial public offering, we issued warrants to purchase shares of our common stock. As of June 30, 2014, all of the warrants have either been exercised or expired in accordance with their terms. Certain of the warrants that were outstanding during 2014 included a provision that provided for a reduction in the warrant exercise price upon subsequent issuances of additional shares of common stock for consideration per share less than the applicable per share warrant exercise price. The warrants containing this provision were deemed to be derivative instruments and as such, were recorded as a liability and marked-to-market at each reporting period. The fair value estimates of these warrants were determined using a Black-Scholes option-pricing model and were based, in part, on subjective assumptions. Non-cash changes in the fair value of the common stock warrant liability from the prior period were recorded as a component of other income and expense.

Results of Operations

Comparison of the Three Months Ended June 30, 2014 and the Three Months Ended June 30, 2015

The following table summarizes our results of operations for each of the three months ended June 30, 2014 and 2015, together with the changes in those items in dollars:

	Three Months Ended June 30,		Dollar Change
	2014	2015	
	(In thousands)		
Licensing revenue	$445	$445	$-
Operating expenses:			
Research and development	14,919	28,295	13,376
General and administrative	7,955	20,974	13,019

Loss from operations	(22,429)	(48,824)	(26,395)
Warrant revaluation income	55,795	-	(55,795)
Other income, net	104	930	825
Net loss	$33,470	$(47,894)	$(81,364)

Licensing Revenue

Licensing revenue was $445,000 for each of the three months ended June 30, 2014 and 2015 resulting from the amortization of the up-front payments under the collaboration agreement with Sumitomo Dainippon.

Research and Development Expenses

Research and development expenses were $14.9 million and $28.3 million for the three months ended June 30, 2014 and 2015, respectively, representing an increase of $13.4 million. This increase in research and development expense primarily reflects:

- increased expenses of $6.6 million related to personnel and activities to support our NDA and MAA filings for OCA in PBC as well as increased development initiatives;
- increased expenses of approximately $2.9 million related to product development and manufacturing;
- increased costs of $1.2 million associated with our INT-767 program;
- increased expenses of approximately $1.0 million from research and discovery initiatives; and
- increased indirect costs of approximately $1.7 million.

General and Administrative Expenses

General and administrative expenses were $8.0 million and $21.0 million in the three months ended June 30, 2014 and 2015, respectively. The $13.0 million increase primarily reflects:

- increased expenses of $6.8 million for personnel and related activities to support our increased development initiatives as well as our pre-commercial activities;
- increased expenses of approximately $2.5 million related to legal, finance and facilities costs to support our growing operations;
- increased expenses of approximately $2.1 million for employee recruitment activities; and
- increased expenses of approximately $1.6 million related to shareholder litigation expenses.

Other Income, Net

Other income, net was primarily attributable to interest income earned on cash, cash equivalents and investment securities, which increased compared to the prior year period as a result of the increase in the investment balances from our April 2014, February 2015 and April 2015 equity financings.

Comparison of the Six Months Ended June 30, 2014 and the Six Months Ended June 30, 2015

The following table summarizes our results of operations for each of the six months ended June 30, 2014 and 2015, together with the changes in those items in dollars:

	Six Months Ended June 30,		Dollar Change
	2014	2015	
	(In thousands)		
Licensing revenue	$851	$1,891	$1,040
Operating expenses:			
Research and development	29,212	56,260	27,048
General and administrative	13,606	34,112	20,506
Loss from operations	(41,967)	(88,481)	(46,514)
Warrant revaluation (expense)	(170,832)	-	170,832

Other income, net	240	1,201	961
Net loss	$(212,559)	$(87,280)	$125,279

Licensing Revenue

Licensing revenue was $851,000 and $1.9 million for the six months ended June 30, 2014 and 2015, respectively. All of the revenue recognized in the six months ended June 30, 2014 related to the amortization of the up-front payments under the collaboration agreement. For the six months ended June 30, 2015, $891,000 resulted from the amortization of the up-front payments under the collaboration agreement with Sumitomo Dainippon and $1.0 million resulted from the milestone achieved in the period.

Research and Development Expenses

Research and development expenses were $29.2 million and $56.3 million for the six months ended June 30, 2014 and 2015, respectively, representing an increase of approximately $27.1 million. This increase in research and development expense primarily reflects:

- increased expenses of $11.2 million related to personnel and activities to support our NDA and MAA filings for OCA in PBC as well as increased development initiatives;
- increased expenses of approximately $4.7 million from research and discovery initiatives;
- increased expenses of approximately $3.9 million related to other development initiatives;
- increased costs of approximately $3.2 million related to product development and manufacturing;
- increased costs of $2.3 million associated with our INT-767 program; and
- increased indirect costs of approximately $1.7 million.

General and Administrative Expenses

General and administrative expenses were $13.6 million and $34.1 million in the six months ended June 30, 2014 and 2015, respectively. The $20.5 million increase primarily reflects:

- increased expenses of $13.3 million for personnel and related activities to support our increased development initiatives as well as our pre-commercial activities;
- increased expenses of approximately $3.5 million related to legal, finance and facilities costs to support our growing operations;
- increased expenses of approximately $2.0 million for employee recruitment activities; and
- increased expenses of approximately $1.7 million related to shareholder litigation expenses.

Other Income, Net

Other income, net was primarily attributable to interest income earned on cash, cash equivalents and investment securities, which increased compared to the prior year period as a result of the increase in the investment balances from our April 2014, February 2015, and April 2015 equity financings, offset by the increases in cash used in operations.

Liquidity and Capital Resources

Sources of Liquidity

As of June 30, 2015, we had an accumulated deficit of $556.2 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.

We have funded our operations primarily through the sale of common stock, preferred stock, convertible notes and warrants and payments received under our collaboration agreements totaling $623.2 million (net of issuance costs of $33.7 million), including $29.7 million in net proceeds from our Series C financing in August 2012, $78.7 million in

net proceeds from our initial public offering in October 2012, $61.2 million in net proceeds from our follow-on public offering in June 2013, $183.5 million in net proceeds from a follow-on public offering in April 2014, $191.6 million in net proceeds from a follow-on public offering in February 2015, $367.3 million in net proceeds from the follow-on offering in April 2015 and the receipt of $17.4 million in up-front payments under our licensing and collaboration agreements with Sumitomo Dainippon and Servier. As of June 30, 2015, we had cash, cash equivalents and investment securities of $732.3 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Currently, our funds are held in cash and money market bank accounts and investments, all of which have maturities of less than two years.

Cash Flows

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

	Six Months Ended June 30,	
	2014	2015
	(In thousands)	
Net cash provided by (used in):		
Operating activities	$(31,728)	$(63,595)
Investing activities	(124,686)	(431,813)
Financing activities	188,012	563,466
Effect of exchange rate changes	-	176
Net increase in cash and cash equivalents	$31,598	$68,234

Operating Activities. The increase in our net cash used in operating activities of approximately $31.9 million during the six months ended June 30, 2015 as compared to the same period last year was primarily a result of increased activities in our business requiring more capital. Net cash used in operating activities of $31.7 million during the six months ended June 30, 2014 was primarily a result of our $212.6 million net loss, offset by the revaluation of warrants of $170.8 million and share-based compensation of $11.2 million. Net cash used in operating activities of $63.6 million during the six months ended June 30, 2015 was primarily a result of our $87.0 million net loss, offset by the add-back of non-cash expenses of $16.4 million for stock-based compensation, the amortization of investment premium of $2.6 million and net changes in operating assets and liabilities of $3.8 million.

Investing Activities. Net cash used in investing activities for the six months ended June 30, 2014 and 2015 was $124.7 million and $431.8 million, respectively. This net increase in cash used in investing activities of approximately $307.1 million is attributed to the increase in the purchases of investments of $362.7 million as a result of investing the proceeds from the February 2015 and April 2015 offerings, offset by the increase in the sale of investments of $59.1 million. The increase in purchases of equipment, improvements and furniture and fixtures of approximately $3.6 million is primarily related to our expansion efforts at our New York office and leasehold improvements in our United Kingdom office.

Financing Activities. Net cash provided by financing activities for the six months ended June 2014 were $188.0 million compared to $563.5 million for the comparable period in 2015. This increase was primarily the result of funds received through the February 2015 and the April 2015 offerings.

Future Funding Requirements

To date, we have not generated any revenue from product sales. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate significant revenue from product sales unless and until we obtain regulatory approval of and commercialize OCA or any of our other product candidates. At the same time, we expect our expenses to increase in connection with our ongoing development activities, particularly as we continue the research, development and clinical trials of, and seek regulatory approval for, our product candidates. We have incurred and expect to incur additional costs associated with operating as a public company and further plan on expanding our operations in the United States, Europe and in other countries such as Canada and Australia. 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.

As of June 30, 2015, we had $732.3 million in cash, cash equivalents and investment securities. We currently project adjusted operating expenses of $240 million in the fiscal year ending December 31, 2015, which excludes stock-based compensation and other non-cash items. This is an increase from the previous projection of $180 million to $200 million in adjusted operating expenses, and represents approximately $170 million of anticipated adjusted operating

expenses in the second half of 2015, with the weighting of these expenses to come in the fourth quarter. The increase is primarily due to accelerated hiring of additional employees and infrastructure buildout supporting our commercial and research and development efforts. These expenses are planned to support the clinical development program for OCA in PBC, NASH and PSC, the expansion of our clinical, regulatory, medical affairs and commercial infrastructure in the United States, Europe and other countries such as Canada and Australia, increased OCA manufacturing activities, as well as the continued development of INT-767 and other preclinical pipeline programs. We anticipate that stock-based compensation expense will represent the most significant non-cash item that is excluded in adjusted operating expenses as compared to operating expenses under U.S. generally accepted accounting principles, or GAAP. Adjusted operating expense is a financial measure not calculated in accordance with GAAP. See "Non-GAAP Financial Measures" for more information. Accordingly, we will continue to require substantial additional capital to continue our clinical development and commercialization activities. Because successful development of our product candidates is uncertain, we are unable to estimate the actual funds required to complete research and development and commercialization of our products under development.

Due to the many variables inherent to the development and commercialization of novel therapies and our rapid growth and expansion, we currently cannot accurately and precisely predict the duration beyond 2015 over which we expect our cash and cash equivalents to be sufficient to fund our operating expenses and capital expenditure requirements. However, we currently believe that our cash and cash equivalents will be sufficient for us to:

- expand our clinical, regulatory, medical affairs and commercial infrastructure in the United States and Europe;
- continue our clinical development of OCA in PBC, NASH and PSC;
- expand our OCA manufacturing activities;
- advance INT-767, including the completion of IND-enabling preclinical studies for INT-767 and the initiation of a Phase 1 clinical trial, and other preclinical pipeline programs; and
- prepare for and initiate the planned commercial launch of OCA in PBC in the United States, certain European countries and Canada in 2016.

We will continue to require substantial additional capital to continue our clinical development, commercialization and other activities. Because successful development and commercialization of our product candidates is uncertain, we are unable to estimate the actual funds we will require to complete research and development and commercialization of our products under development.

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

- the willingness of the FDA and the EMA to accept the POISE trial, which is our completed Phase 3 clinical trial for PBC, as well as our other completed and planned clinical and preclinical studies and other work, as the basis for the review and marketing approval of OCA for PBC;
- the progress, costs, results of and timing of our recently initiated confirmatory clinical outcomes trial of OCA for the treatment of PBC, the completion of which we expect will not be a condition to the receipt of marketing approval in the United States or the European Union;
- the design of our overall Phase 3 program in NASH, which includes our Phase 3 REGENERATE trial of OCA in non-cirrhotic NASH patients with liver fibrosis and may include Phase 3 trials in other subpopulations with NASH such as those with cirrhosis;
- the progress, costs, results of and timing of our Phase 3 REGENERATE trial of OCA in non-cirrhotic NASH patients with liver fibrosis, other supporting trials and studies necessary to support anticipated filings for marketing approval of OCA in non-cirrhotic NASH patients with liver fibrosis, including the sufficiency of one pivotal clinical trial for marketing approval or the acceptability of a surrogate endpoint for accelerated approval of OCA in this patient population, and any additional trials we may conduct in other subpopulations of NASH patients;
- the progress, costs, results of and timing of clinical development of OCA for other indications, including our Phase 2 trial of OCA in PSC and biliary atresia;
- the significant expansion of our operations, personnel and the size of our company and our need to continue to expand;
- the outcome, costs and timing of seeking and obtaining FDA, EMA and any other regulatory approvals;
- the number and characteristics of product candidates that we pursue, including our product candidates in preclinical development, such as INT-767 and INT-777;
- the ability of our product candidates to progress through pre-clinical and clinical development successfully and in a timely manner;
- the expansion of our research and development activities;
- the costs and timing of commercialization activities, including product sales, marketing and distribution, for any of our product candidates that receive marketing approval;
- the costs associated with securing and establishing manufacturing capabilities and procuring the materials necessary for our product candidates;
- 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, scientific and medical, commercial and other qualified personnel and the substantial cost of retaining such additional personnel;
- the effect of competing technological and market developments;
- our plan to expand our operations into Europe and other countries such as Canada and Australia and the manner in which we implement our expansion plan;
- our need to implement and maintain internal systems, software and infrastructure, including those to assist in our financial and reporting, clinical development and commercialization efforts and to support our existing and expanding personnel; 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.

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

Contractual Obligations and Commitments

Other than as described below, there have been no material changes to our contractual obligations and commitments outside the ordinary course of business from those disclosed under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations-Contractual Obligations and Commitments” in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 2, 2015.

In February 2015, we entered into an underlease with Merck Sharp & Dohme Limited for our new office in the King's Cross area of London, United Kingdom. The lease provides us with approximately 6,000 rentable square feet in London for office space. The lease term is anticipated to end in June 2019. The annual rent is £470,608, payable quarterly. We are also required to pay value added tax, or VAT, on the rent. We are responsible for a portion of the insurance, certain service charges and taxes for the building based on the floor area rented by us. As security for the underlease, we have provided the landlord with a rent deposit in the amount of £705,912 (or approximately $1.1 million), plus applicable VAT. The amount of the deposit may be reduced to £470,608 within 30 days after April 30, 2016 if there are no outstanding payments due and there are no material breaches of the underlease that have not been unremedied in respect of which a drawdown notice has been served and has expired.

Off-Balance Sheet Arrangements

As of June 30, 2015, we did not have any off-balance sheet arrangements as defined under the rules of the Securities and Exchange Commission.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates and there have been no material changes since our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 2, 2015.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our disclosure controls are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, or the Exchange Act, are recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. In designing and evaluating our disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act as of June 30, 2015, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures

were adequate and effective.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act), identified in connection with the evaluation of such internal control, that occurred during the three months ended June 30, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

In 2013, the Committee of Sponsoring Organizations, or COSO, updated its 1992 *Internal Control – Integrated Framework* which is relied on to achieve compliance with the Sarbanes-Oxley Act. The new framework requires 17 principles of internal control to be present and functioning before an entity can assess that it has adequate control over financial reporting. We delayed the implementation of the 2013 framework until 2015, primarily because of the implementation of a new enterprise resource planning system in the second half of 2014. We feel the additional time to implement the 2013 framework will provide us the time to evaluate and address the risks to our organization in view of our changing size and global presence.

PART II
OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time we are party to legal proceedings in the course of our business in addition to those described below. We do not, however, expect such other legal proceedings to have a material adverse effect on our business, financial condition or results of operations.

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

The lawsuits allege that we made material misrepresentations and/or omissions of material fact in our public disclosures during the period from January 9, 2014 to January 10, 2014, in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder. The alleged improper disclosures relate to our January 9, 2014 announcement that the FLINT trial had been stopped early based on a pre-defined interim efficacy analysis. Specifically, the lawsuits claim that the January 9, 2014 announcement was misleading because it did not contain information regarding certain lipid abnormalities seen in the FLINT trial in OCA-treated patients compared to placebo. On April 22, 2014, two individuals each moved to consolidate the cases and a lead plaintiff was subsequently appointed by the Court. On June 27, 2014, the lead plaintiff filed an amended complaint on behalf of the putative class as contemplated by the order of the Court. On August 14, 2014, the defendants filed a motion to dismiss the complaint. Oral arguments on the motion to dismiss were held on February 24, 2015. On March 4, 2015, the defendants' motion to dismiss was denied by the Court. The defendants answered the amended complaint on April 13, 2015. The parties are currently undergoing discovery in relation to this matter.

The lead plaintiff seeks unspecified monetary damages on behalf of the putative class and an award of costs and expenses, including attorneys' fees.

We believe that we have valid defenses to the claims in the lawsuit and intend to deny liability and defend ourselves vigorously. At this time, no assessment can be made as to the likely outcome of these lawsuits or whether the outcome will be material to us. Therefore, we have not accrued for any loss contingencies related to these lawsuits.

Item 1A. Risk Factors.

Other than as discussed below, there have been no material changes to our risk factors contained in our Annual Report on Form 10-K for the period ended December 31, 2014 and any updates to those risk factors contained in our subsequent periodic and current reports filed with the Securities and Exchange Commission. The risk factors described below update and supersede the corresponding risk factors contained in our Annual Report on Form 10-K. For a further discussion of our Risk Factors, refer to the "Risk Factors" discussion contained in such filings.

Risks Related 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 incurred net losses in each year since our inception, including net losses of $43.6 million, $67.8 million and $283.2 million for the years ended December 31, 2012, 2013 and 2014, respectively, and $87.0 million for the six months ended June 30, 2015. To date, we have financed our operations primarily through private placements of our convertible preferred stock, convertible notes and warrants to purchase common stock, public offerings of our common stock and payments received under our licensing and collaboration agreements with Sumitomo Dainippon Pharma Co. Ltd., or Sumitomo Dainippon, and Les Laboratoires Servier and Institut de Recherches Servier, which are collectively referred to as Servier. At June 30, 2015, we had $732.3 million in cash, cash equivalents and investment securities.

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, protecting our intellectual property and engaging in activities to prepare for the commercialization of our product candidates. We do not have any products approved for sale and 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 in the United States and Europe to support our product development and commercialization efforts and operations as a public company. We anticipate that any such losses could be significant for the next several years as we continue our confirmatory clinical outcomes trial of OCA in primary biliary cirrhosis, or PBC, continue our long-term safety extension phases of our clinical trials of OCA in PBC, continue our Phase 3 clinical program of OCA in nonalcoholic steatohepatitis, or NASH, continue our Phase 2 clinical trial of OCA for primary sclerosing cholangitis, or PSC, and finalize other planned activities for regulatory approval of OCA in PBC. We also expect that continuing the development of OCA in additional diseases, such as biliary atresia, a rare pediatric disease characterized by deficient bile duct development. We also plan on initiating a clinical trial to assess the lipid metabolic effects of OCA and the effects of concomitant statin administration in NASH patients during 2015. Furthermore, we plan to complete IND-enabling studies of INT-767, an earlier stage product candidate for which we plan to initiate, Phase 1 clinical trial by the end of 2015. 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. We also anticipate that we will continue to increase our product development, scientific, commercial and administrative personnel significantly and expand our facilities and infrastructure in the United States and abroad as part of our growth strategy.

Our ability to generate profits from operations and become profitable will depend on our ability to obtain marketing approval for, and commercialize, our product candidates. We do not expect to generate significant revenues unless and until we obtain marketing approval for, and commercialize, OCA for the treatment of PBC and other indications. This will require us to be successful in a range of challenging activities, including:

- obtaining approval to market OCA for the treatment of PBC, NASH and other indications and patient populations;
- expanding our manufacturing of commercial supply for OCA;
- establishing sales, marketing and distribution capabilities to effectively market and sell OCA in the United States and Europe; and
- negotiating and securing reimbursement from third-party payors for OCA.

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. Our 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 and commercialization, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. 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. In June 2015, we completed our filings for marketing approval of OCA in PBC in the United States and Europe. If we receive marketing approval from regulatory authorities, we plan to initiate the commercial launch of OCA in PBC in the United States and certain European countries in 2016. We anticipate incurring significant expenses as we prepare for the potential commercialization of OCA in PBC, including significant expenses to establish our sales, marketing and distribution capabilities and increase our drug manufacturing activities. 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. We also anticipate incurring significant expenses in connection with our planned increase in our product development, scientific, commercial and administrative personnel and expansion of our facilities and infrastructure in the United States and abroad.

As of June 30, 2015, we had $732.3 million in cash, cash equivalents and investment securities. We currently project adjusted operating expenses of $240 million in the fiscal year ending December 31, 2015, which excludes stock-based compensation and other non-cash items. These expenses are planned to support the clinical development program for OCA in PBC, NASH and PSC, the expansion of our clinical, regulatory, medical affairs and commercial infrastructure

in the United States and Europe, increased OCA manufacturing activities, as well as the continued development of INT-767 and other preclinical pipeline programs. We anticipate that stock-based compensation expense will represent the most significant non-cash item that is excluded in adjusted operating expenses as compared to operating expenses under U.S. generally accepted accounting principles, or GAAP. Adjusted operating expense is a financial measure not calculated in accordance with GAAP. See “Non-GAAP Financial Measures” for more information. Accordingly, we will continue to require substantial additional capital to continue our clinical development and commercialization activities. Because successful development of our product candidates is uncertain, we are unable to estimate the actual funds we will require to complete research and development and commercialize our products under development.

Due to the many variables inherent to the development and commercialization of novel therapies, such as the risks described in the “Risk Factors” section of our Annual Report on Form 10-K and this Quarterly Report on Form 10-Q, and our rapid growth and expansion, we currently cannot accurately or precisely predict the duration beyond 2015 over which we expect our cash and cash equivalents to be sufficient to fund our operating expenses and capital expenditure requirements. However, we currently believe that our cash and cash equivalents will be sufficient for us to:

- expand our clinical, regulatory, medical affairs and commercial infrastructure in the United States and Europe;

- continue and expand our clinical development programs for OCA in PBC, NASH and PSC, such as initiating and/or continuing, but not completing, our planned Phase 3 clinical program for OCA in NASH, our planned clinical trial characterizing lipid metabolic effects of OCA and cholesterol management effects of concomitant statin administration in NASH patients, our ongoing Phase 2 clinical trial of OCA for PSC, and our ongoing confirmatory clinical outcomes trial of OCA in PBC;
- advance the continued development of INT-767, including the completion of IND-enabling preclinical studies for INT-767 and the initiation of a Phase 1 clinical trial, and other preclinical compounds;
- continue our activities to support our recently completed NDA and MAA filings to receive marketing authorization for OCA in PBC in the United States and Europe, but not complete our filings for marketing authorization in any other indication;
- increase OCA manufacturing activities, including investing in supply chain and product development, preparing for PBC commercial launch and planning for the continuation of our clinical program in NASH, but not manufacture the supply needed for any potential commercial launch of OCA in NASH; and
- prepare for and, if we obtain marketing approval on a timely basis, initiate the commercial launch of OCA in PBC in both the United States and certain European countries in 2016, but not commercially launch OCA in PBC in other countries across the world.

Accordingly, we will continue to require substantial additional capital to continue our clinical development, commercialization and other activities. Because successful development and commercialization 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:

- the willingness of the FDA and EMA to accept the POISE trial, which is our completed phase 3 clinical trial for PBC, as well as our other completed and planned clinical and preclinical studies and other work, as the basis for review and marketing approval of OCA for PBC;
- the progress, costs, results of and timing of our recently initiated confirmatory clinical outcomes trial of OCA for the treatment of PBC, the completion of which we expect will not be a condition to the receipt of marketing approval in the United States or the European Union;
- the design of our overall Phase 3 program in NASH, which includes our Phase 3 REGENERATE trial of OCA in non-cirrhotic NASH patients with liver fibrosis and may include Phase 3 trials in other subpopulations with NASH such as those with cirrhosis;
- the progress, costs, results of and timing of our Phase 3 REGENERATE trial of OCA in non-cirrhotic NASH patients with liver fibrosis, other supporting trials and studies necessary to support anticipated filings for marketing approval of OCA in non-cirrhotic NASH patients with liver fibrosis, including the sufficiency of one pivotal clinical trial for marketing approval or the acceptability of a surrogate endpoint for accelerated approval of OCA in this patient population, and any additional trials we may conduct in other subpopulations of NASH patients;
- the progress, costs, results of and timing of clinical development of OCA for other indications, including our Phase 2 trial of OCA in PSC and biliary atresia;
- the significant expansion of our operations, personnel and the size of our company and our need to continue to expand;
- the outcome, costs and timing of seeking and obtaining FDA, EMA and any other regulatory approvals;

- the number and characteristics of product candidates that we pursue, including our product candidates in preclinical development, such as INT-767 and INT-777;
- the ability of our product candidates to progress through pre-clinical and clinical development successfully and in a timely manner;
- the expansion of our research and development activities;
- the costs and timing of commercialization activities, including product sales, marketing and distribution, for any of our product candidates that receive marketing approval;
- the costs associated with securing and establishing manufacturing capabilities and procuring the materials necessary for our product candidates;
- acceptance of our product candidates by the market and third-party payors;
- 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, scientific and medical, commercial and other qualified personnel and the substantial cost of retaining such additional personnel;
- the effect of competing technological and market developments;
- our need to implement and maintain internal systems, software and infrastructure, including those to assist in our financial and reporting, clinical development and commercialization efforts and to support our existing and expanding personnel; 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.

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 our planned activities, including research and development programs and commercialization activities. 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 payments received under our collaboration and license agreements with Sumitomo Dainippon and Servier. Additional payments under each of the Sumitomo Dainippon and Servier agreements are based on the exercise of optional rights held by our collaborators under the agreements or 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 Sumitomo Dainippon and Servier under their respective collaboration and license agreements are uncertain because Sumitomo Dainippon or Servier, as the case may be, may choose not to exercise their optional rights under the agreements or continue research or development 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 and engaging in pre-commercial activities for OCA in PBC. We have not yet obtained regulatory approvals for any of our product candidates. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history or approved products on the market. Our financial condition and operating results have varied significantly in the past and are expected to continue to significantly fluctuate from quarter-to-quarter or year-to-year due to a variety of factors, many of which are beyond our control.

Factors relating to our business that may contribute to these fluctuations include:

- any delays in regulatory review and approval of our product candidates in clinical development, including our ability to receive approval from the FDA and the EMA for OCA for the treatment of PBC based on our 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, including those due to PBC and PSC being rare diseases and NASH currently requiring an invasive liver biopsy for diagnosis;
- the success of our clinical trials through all phases of clinical development, such as the success of our Phase 3 REGENERATE trial of OCA in non-cirrhotic NASH patients with liver fibrosis;
- potential side effects of our product candidates that could delay or prevent approval or cause an approved drug to be taken off the market;
- the required timeframe for us to receive and analyze data from our clinical trials;
- 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 reimbursement for our products and the extent to which such coverage or reimbursement will be provided;
- our ability to adhere to clinical trial 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, securities and other 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 and improve our company's infrastructure, systems and controls;
- potential product liability claims; and
- our ability to obtain and maintain adequate insurance coverage.

Risks Related 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 and commercialize our product candidates.

We are initially developing OCA for the treatment of patient populations with chronic liver and other diseases, with a current principal focus on PBC, NASH and PSC, and 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, particularly for the treatment of PBC and NASH, 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 an NDA from the FDA or an MAA from the EMA, respectively. While we have completed the submissions of our NDA and MAA for OCA in PBC, we have not yet received marketing authorization from either the FDA or EMA 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 an NDA or an 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. Even after the submission of an 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. Approvals may also be conditional upon the completion of one or more clinical trials. 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. Regulatory approval is also dependent on successfully passing regulatory inspection of our company, our clinical sites and key vendors and to ensure compliance with applicable good clinical, laboratory and manufacturing practices regulation. Critical findings could jeopardize or delay the approval of the NDA or MAA.

We have completed a randomized, placebo-controlled Phase 3 trial of OCA in PBC patients, which we refer to as the POISE trial, and two randomized, placebo-controlled Phase 2 trials of OCA in PBC patients, one with OCA in combination with ursodiol and one with OCA as monotherapy, and we are finalizing other preclinical and clinical studies required to complete the filings. Furthermore, we will need to complete a number of clinical trials and other studies for the continued development of OCA in indications other than PBC. For example, we are currently planning to initiate our Phase 3 REGENERATE trial of OCA in non-cirrhotic NASH patients with liver fibrosis and intend to conduct a number of supporting studies and trials such as a Phase 2 trial characterizing the lipid metabolic effects of OCA and cholesterol management effects of concomitant statin administration in NASH patients. In each of these cases, our ability to obtain the approvals necessary to commercialize our product candidates will depend on our ability to conduct and complete these additional trials as well as assemble various other data to complete our regulatory filings for OCA in the relevant indication or patient population.

There can be no assurance that we will be able to receive marketing approval for OCA in PBC or that we will be able to complete our regulatory filings for any other indication on a timely basis or at all. We cannot predict whether our trials and studies as to NASH or any other indication or patient population will be successful or whether regulators will agree with our conclusions regarding the preclinical studies and clinical trials we have conducted to date or require us to conduct additional studies or trials. For example, while OCA received breakthrough therapy designation from the FDA in January 2015 for the treatment of NASH patients with liver fibrosis, we do not know if one pivotal clinical trial will be sufficient for marketing approval or if regulators will ultimately agree to a surrogate endpoint for accelerated approval of OCA for the treatment of NASH. While the interim histological endpoint is similar to that in the Phase 2b clinical trial for the treatment of NASH, known as the FLINT trial, sponsored by the U.S. National Institute of Diabetes and Digestive and Kidney Diseases, or NIDDK, a part of the National Institutes of Health, our Phase 3 REGENERATE trial has different trial designs. For example, the REGNERATE trial will include the following interim co-primary endpoints which are intended to serve as the basis for seeking marketing approvals in the United States, Europe and other countries: (i) the proportion of OCA-treated patients relative to placebo achieving at least one stage of liver fibrosis improvement with no worsening NASH and (ii) the proportion of OCA-treated patients relative to placebo achieving NASH resolution with no worsening of liver fibrosis. The REGENERATE trial will also remain blinded after the interim analysis and continue to follow patients until the occurrence of a pre-specified number of adverse liver-related clinical events, including progression to cirrhosis, to confirm clinical benefit on a post-marketing basis.

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 are developing product candidates for the treatment of rare diseases or diseases for which there are no or limited therapies and for some of which there is little clinical experience, and our development approach involves new endpoints and methodologies. As a result, there is increased risk that we will not be able to gain agreement with regulatory authorities regarding an acceptable development plan, the outcome of our clinical trials will not be favorable or that, even if favorable, regulatory authorities may not find the results of our clinical trials to be sufficient for marketing approval.

Currently, there are no approved therapies for NASH or PSC. In PBC, 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. As a result, the design and conduct of clinical trials for these diseases and other indications we may pursue will be subject to increased risk.

The FDA generally requires two pivotal clinical trials to approve an NDA. Furthermore, for full approval of an NDA, the FDA requires a demonstration of efficacy based on a clinical benefit endpoint. Under Subpart H regulations, the FDA can grant accelerated approval based on a surrogate reasonably likely to predict clinical benefit. The POISE primary endpoint is a surrogate endpoint that we believe is reasonably likely to predict clinical benefit, therefore meeting the FDA's Subpart H requirements for consideration under its accelerated approval regulation. While we completed the submission of the NDA in June 2015, formal review of the NDA will not commence until 60 days after submission. It is unlikely we will receive definitive written guidance from the FDA prior to formal review of our NDA as to the acceptability of the POISE trial surrogate endpoint to support an approval of OCA for the treatment of PBC. Although the results from our POISE trial are highly significant and supported by two controlled Phase 2 trials, our POISE trial and our regulatory submissions package may nonetheless not be sufficient to support approval in the United States. We anticipate that similar risks will apply to other indications for which we intend to seek marketing approval for our product candidates under accelerated approval regulations. For example, we will face these risks for OCA for the treatment of NASH because of our plan to seek accelerated approval based on the REGENERATE trial which incorporates interim co-primary surrogate endpoints.

In order to support the clinical utility of the surrogate endpoint for OCA as a treatment for PBC, we have sponsored an independent study pooling and analyzing long-term PBC patient data from a number of leading PBC academic centers, which are referred to as the Global PBC Study Group. Furthermore, an academic consortium in the United Kingdom has published the results of another large observational study in PBC patients in the United Kingdom. Although we believe the results of both studies are supportive of the clinical utility of our surrogate endpoint for the use of OCA in PBC, the supporting data may still not be accepted by the FDA in its consideration of the adequacy of our surrogate endpoint under an NDA for OCA for the treatment of PBC. In addition to the risk around the acceptability of the surrogate biochemical endpoint to support accelerated approval, there are quality assurance risks

around the data supporting assessment of the biochemical endpoint. It is possible that key parameters such as the validation of the assay and consistency across laboratories will not be acceptable to FDA and could delay or jeopardize approval of the NDA.

The FDA has also informed us that, even if it provides us an accelerated approval for OCA, we will be required to conduct a post-approval 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. Following discussions with the FDA, we initiated the trial in December 2014. There can be no assurance that our clinical outcomes confirmatory trial will confirm that the surrogate endpoints used for accelerated approval will eventually show an adequate correlation with clinical outcomes. If the clinical outcomes confirmatory trial fails to show such adequate correlation, we may not be able to maintain our previously granted marketing approval for OCA in PBC.

Likewise, we will not receive definitive feedback from the EMA prior to formal review of our MAA as to the acceptability of the POISE trial endpoint to support a marketing authorization of OCA for the treatment of PBC. It is also possible that any marketing authorization we receive from the EMA for OCA for the treatment of PBC could be conditional on post-approval studies and not considered a full approval. Our ability to obtain and maintain conditional marketing authorization in the European Union will be limited to specific circumstances and subject to several conditions and obligations, if obtained at all, including the completion of a clinical outcomes trial to confirm the clinical benefit of OCA in PBC. Conditional marketing authorizations based on incomplete clinical data may be granted for a limited number of listed medicinal products for human use, including products designated as orphan medicinal products under European Union law, if (1) the risk-benefit balance of the product is positive, (2) it is likely that the applicant will be in a position to provide the required comprehensive clinical trial data, (3) unmet medical needs will be fulfilled and (4) the benefit to public health of the immediate availability on the market of the medicinal product outweighs the risk inherent in the fact that additional data are still required. Specific obligations, including with respect to the completion of ongoing or new studies, and with respect to the collection of pharmacovigilance data, may be specified in the conditional marketing authorization. Conditional marketing authorizations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions.

Our Phase 3 REGENERATE trial of OCA in non-cirrhotic NASH patients with liver fibrosis incorporates interim co-primary surrogate endpoints that may serve as the basis for a supplemental NDA filing for accelerated approval in the United States and approval in Europe. Accelerated approval in the United States and conditional approval in the European Union for OCA in NASH are subject to similar risks as discussed above in relation to OCA for PBC. The primary endpoint in the Phase 2b FLINT trial of OCA in NASH patients was based on liver biopsy and was 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 and the co-primary endpoints for our REGENERATE trial are: (i) the proportion of OCA-treated patients relative to placebo achieving at least one stage of liver fibrosis improvement with no worsening NASH and (ii) the proportion of OCA-treated patients relative to placebo achieving NASH resolution with no worsening of liver fibrosis. Currently, other biopharmaceutical companies are enrolling or have initiated trials in certain subpopulations of NASH patients based on different endpoints from those in the FLINT and REGENERATE trials. Although the FDA acknowledged at recent workshops the possibility of granting accelerated approval for NASH therapies using surrogate endpoints, with potential examples including histological improvement, using the NAS or another scoring system, histological resolution of NASH, or improvements in fibrosis in pre-cirrhotic patients with NASH, the FDA did not provide any formal regulatory guidance on approvable endpoints and may not accept a surrogate endpoint for OCA for the treatment of NASH.

The FDA generally requires two pivotal clinical trials to approve an NDA. Therefore, even if we achieve favorable results in a single Phase 3 clinical trial, the FDA may not accept this one trial as an adequate basis for approval and require that we conduct and complete a second Phase 3 clinical trial before considering an NDA for any of the indications for which we may seek marketing approval for our product candidates. Our NDA for OCA for the treatment of PBC patients who have an inadequate response to or are intolerant of ursodiol will be based on the results of three clinical trials — the POISE trial and two Phase 2 trials. It is possible that our final 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 particular because we have only conducted a single Phase 3 clinical trial 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. A similar risk applies if we seek marketing approval of OCA for non-cirrhotic NASH patients with liver fibrosis based on the interim results of our REGENERATE trial. Our regulatory pathway for OCA for the treatment of NASH will depend upon our discussions with the FDA and EMA. As a result, we may face difficulty in designing an acceptable registration strategy around REGENERATE or any other trials in different subpopulations of NASH patients. In addition, since the design of the REGENERATE trial deviates from that of the FLINT trial, there is an increased risk that the results of the REGENERATE trial would differ from the FLINT results.

The EMA and regulatory authorities in other countries in which we may seek approval for, and market, OCA or our other product candidates 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 any of our targeted indications, the labeling for our product candidates in the United States, Europe or other countries in which we seek approval may include limitations that could impact the commercial success of our product candidates.

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

Delays in the commencement, enrollment and completion of clinical trials could increase our product development costs or limit the regulatory approval of our product candidates. We initiated our clinical outcomes confirmatory trial in PBC in December 2014. We also initiated our Phase 2 trial in PSC in December 2014. We completed the design of our Phase 3 trial in non-cirrhotic NASH patients with liver fibrosis in May 2015 and are working to initiate the trial. The results from these trials may not be available when we expect 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 the related indication, in which case we would require additional funding. In addition, our clinical programs are subject to a number of variables and contingencies, such as the results of other trials or regulatory interactions that may result in a change in timing. As such, we do not know whether any future trials or studies of our other product candidates, including our clinical outcomes 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 or lack of adequate funding to continue the clinical trial due to unforeseen costs or other business decisions;
- 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;

- the delay in receiving results from or the failure to achieve the necessary results in other clinical trials;
- 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 or any determination that a clinical trial presents unacceptable health risks;
- 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 Sumitomo Dainippon and Servier or investigators leading clinical trials on our product candidates;
- 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 trial, the risks of procedures that may be required as part of the trial, such as a liver biopsy, 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, if we or any of our collaborators are required to conduct additional clinical trials or other preclinical studies of our product candidates beyond those contemplated, our ability to obtain regulatory approval of these product candidates and generate revenue from their sales would be similarly harmed.

Clinical failure can occur at any stage of clinical development. The results of earlier clinical trials are not necessarily predictive of future results and any product candidate we, Sumitomo Dainippon, 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 and at other stages of clinical development, even after seeing promising results in earlier clinical trials.

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 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, the prospects for approval of OCA would be materially and adversely affected and our business would be harmed.

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 or differences 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.

We believe that the results of our POISE trial and our long-term safety extension trials in PBC patients, which include patients who currently have been on OCA therapy for more than four years, demonstrate that OCA produces a durable therapeutic response. We completed our filings for marketing approval of OCA in PBC in the United States and the European Union in June 2015. We cannot assure you that our POISE trial results will result in our receiving marketing approval for OCA in PBC or that our planned clinical outcomes confirmatory trial of OCA in PBC will demonstrate a correlation of biochemical therapeutic response in patients taking OCA with a significant reduction in adverse clinical events over time.

In December 2014, we received comprehensive datasets from the FLINT trial. The Phase 2 trial in NASH currently being conducted in Japan by our collaborator Sumitomo Dainippon involves different doses of OCA being administered to the trial subjects than those utilized in FLINT. As a result, the positive efficacy results seen in FLINT may not be replicated in the Japanese trial or any future trial we may conduct in NASH. In addition, since the design of the REGENERATE trial deviates from that of the FLINT trial, there is an increased risk that the results of the REGENERATE trial would differ from the FLINT results. Even though OCA has been granted breakthrough therapy designation by the FDA, we do not know if one pivotal clinical trial will be sufficient for marketing approval or if regulators will agree to a surrogate endpoint for accelerated approval of OCA for the treatment of NASH. As a result, it may take longer than anticipated to initiate and complete the Phase 3 REGENERATE trial or our Phase 3 program in NASH for other patient subpopulations.

Our product candidates may have undesirable side effects which may delay or prevent marketing approval, or, if approval is received, require our product candidates 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 endogenous human bile acid CDCA and cholic acid, 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 in PBC were pruritus, or itching, fatigue, headaches, nausea, constipation and diarrhea. In our Phase 2 PBC clinical trial of OCA in combination with ursodiol, approximately 8% of the patients enrolled in the 10 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. In our POISE trial, pruritus, generally mild to moderate, was the most frequently reported adverse event associated with OCA treatment and was observed in 38% of patients on placebo, 68% of patients in the 10 mg OCA group and 56% of patients in the OCA titration group (5 mg to 10 mg). Eight patients discontinued due to pruritus, of whom none were in the placebo group, seven (10%) patients were in the 10 mg OCA group and one (1%) patient was in the OCA titration group (in a patient who had titrated up to 10 mg). Pruritus also has been observed in other clinical trials of OCA.

Based on information in the manuscript for the FLINT trial published in November 2014, pruritus occurred more frequently in the OCA treatment group than in the placebo treatment group (23% vs. 6%, $p < 0.001$) and at a higher grade (predominately moderate pruritus), but resulted in only one patient discontinuation in the OCA treatment group. In the FLINT trial, OCA treatment was associated with changes in serum lipid levels, including increases in total cholesterol and LDL cholesterol and a decrease in HDL cholesterol, that were observed within 12 weeks of initiating treatment, peaked and then decreased in magnitude while on treatment, and reversed further during the 24-week post-treatment period. As previously disclosed, these changes in cholesterol levels, along with achieving the pre-defined efficacy criteria, played a role in the decision of the FLINT data and safety monitoring board to terminate the treatment phase of FLINT, and the publication of the FLINT results has noted the need for further study of these changes. We intend to initiate a Phase 2 trial characterizing the lipid metabolic effects of OCA and cholesterol management effects of concomitant statin administration in NASH patients in 2015. There were two patient deaths in the FLINT trial that were previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2013, and neither death was considered related to OCA treatment.

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. 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, NASH, PSC, biliary atresia and other potential indications.

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.

In addition, our drug candidates are being developed as potential treatments for severe, life threatening diseases and, as a result, our trials will necessarily be conducted in a patient population that will be more prone than the general population to exhibit certain disease states or adverse events. It may be difficult to discern whether certain events or symptoms observed during our trials were due to our drug candidates or placebo, resulting in our company and our development programs being negatively affected even if such events or symptoms are ultimately determined to be unlikely related to our drug candidates. We further 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.

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, Sumitomo Dainippon, 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.

Breakthrough therapy designation for OCA may not lead to faster development or regulatory processes nor does it increase the likelihood that OCA will receive marketing approval for NASH.

If a drug is intended for the treatment of a serious or life-threatening condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development, the FDA may grant a breakthrough therapy designation. Breakthrough therapy designation is intended to facilitate the development, and expedite the review of such drugs, but the breakthrough therapy designation does not assure any such qualification or ultimate marketing approval by the FDA.

In January 2015, we received breakthrough therapy designation for OCA in the treatment of NASH patients with fibrosis. There is no guarantee that the receipt of breakthrough therapy designation will result in a faster development process, review or approval for OCA in fibrotic NASH patients or increase the likelihood that OCA will be granted marketing approval for fibrotic NASH patients. Likewise, any future breakthrough therapy designation for any other potential indication of OCA neither guarantees a faster development process, review or approval nor improves the likelihood of the grant of marketing approval by FDA for any such potential indication of OCA compared to drugs considered for approval under conventional FDA procedures. In addition, the FDA may withdraw any breakthrough therapy designation at any time. We may seek a breakthrough therapy designation for other of our product candidates, but the FDA may not grant this status to any of our proposed product candidates.

We may not be able to obtain or maintain orphan drug exclusivity for our product candidates, if approved, which would cause our revenues to suffer.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs and biologics for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug or biologic intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same product for that time

period. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a product no longer meets the criteria for orphan drug designation or if the product is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition. In addition, it is possible that orphan drug designation in Europe will not be maintained following approval if the EMA determines that the product does not satisfy the requisite criteria including demonstration of significant clinical benefit.

Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different products can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same product for the same condition if the FDA concludes that the later product is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

Reimbursement decisions by third-party payors may have an adverse effect on pricing and market acceptance of our product candidates, if approved. If there is not sufficient reimbursement for our products or they are not covered at all, 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, reimbursement policies could reduce the demand for, or the price paid for, our products. If reimbursement is not available or is available on a limited basis, we may not be able to successfully commercialize OCA or any other product candidates that we develop.

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

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

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, ACA, became law in the United States. The goal of ACA is to reduce the cost of health care and substantially change the way health care is financed by both governmental and private insurers. While we cannot predict what impact on federal reimbursement policies this legislation will have in general or on our business specifically, the ACA may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of OCA or any future product candidates. In addition, although the United States Supreme Court 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 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 and are enacting more stringent regulations. These laws include false claims and anti-kickback statutes. If we market our products and our products are paid for by governmental programs, it is possible that some of our business activities could be subject to challenge under one or more of these laws.

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

safe harbor. Most states also have statutes or regulations similar to the federal anti-kickback law and federal false claims laws, which apply to items and services covered by Medicaid and other state programs, or, in several states, apply regardless of the payor. Administrative, civil and criminal sanctions may be imposed under these federal and state laws.

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

If the FDA and EMA and other regulatory agencies do not approve the manufacturing facilities of our future contract manufacturers for commercial production on a timely basis or at all, we may not be able to commercialize any of our product candidates or commercialization of our product candidates could be delayed.

We do not intend to manufacture the pharmaceutical products that we plan to sell. We currently have agreements with a contract manufacturer for the production of the active pharmaceutical ingredients and the formulation of sufficient quantities of drug product for the confirmatory outcomes trial and the long-term safety extension phase of the POISE trial for OCA in PBC, our Phase 3 NASH program for OCA and the other trials and preclinical studies that we plan to conduct prior to seeking regulatory approval. If our contract manufacturer should cease to provide services to us for any reason, we likely would experience delays in advancing our clinical trials while we identify and qualify one or more replacement suppliers and we may be unable to obtain replacement supplies on terms that are favorable to us.

We do not have agreements for commercial supplies of OCA or any of our other product candidates and we may not be able to reach agreements with these or other contract manufacturers for sufficient supplies to commercialize OCA if it is approved. Additionally, the facilities used by any contract manufacturer to manufacture OCA or any of our other product candidates must be the subject of a satisfactory inspection before the FDA or the regulators in other jurisdictions approve the product candidate manufactured at that facility. We are completely dependent on these third-party manufacturers for compliance with the requirements of U.S. and non-U.S. regulators for the manufacture of our finished products. If our manufacturers cannot successfully manufacture material that conform to our specifications and current good manufacturing practice requirements of any governmental agency whose jurisdiction to which we are subject, our product candidates will not be approved or, if already approved, may be subject to recalls.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured the product candidates, including:

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

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

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

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

Even if our product candidates receive regulatory approval, we will still be subject to strict regulatory requirements governing manufacturing and marketing of our products and, as a result, we could 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, Sumitomo Dainippon, Servier or our potential future collaborators;
- impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products.

Risks Related to Our Business and Strategy

We have been significantly expanding our operations and the size of our company and will need to continue our expansion. We may experience difficulties in managing our significant growth.

From December 31, 2014 to June 30, 2015, our employee base has grown from 136 to 203 employees. Of the 203 employees as of June 30, 2015, 102 employees were in our development group, 61 employees were in our commercial group and 40 employees were in our corporate group. At June 30, 2015, 173 employees were based in the United States and 30 employees were based in Europe. As we advance our programs for OCA in PBC, NASH and PSC and seek regulatory approval in the United States and elsewhere, 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. We will also need to grow our commercial capabilities, which will require us to hire additional personnel, both for our ongoing pre-commercial activities and for the launch and ongoing marketing and sale of any product candidate for which we obtain marketing approval. In addition, to meet our obligations as a public company and to support the anticipated growth in the other functions at our company, we will need to increase our general and administrative capabilities. We are also expanding our operations geographically and have recently formed a wholly-owned subsidiary in the United Kingdom which we anticipate will serve as our headquarters for our operations in Europe and anticipate building out our European operations. 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 in the United States, Europe and in other jurisdictions;
- manage our clinical programs effectively, which we anticipate being conducted at numerous clinical sites across the world, and advance our other development efforts;
- develop and expand our 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.

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

Recent Sales of Unregistered Securities

Set forth below is information regarding securities sold by us during the three months ended June 30, 2015 that were not registered under the Securities Act of 1933, as amended, or Securities Act. Also included is the consideration, if any, received by us for the securities and information relating to the section of the Securities Act, or rule of the Securities and Exchange Commission, under which exemption from registration was claimed.

Between January 1 and June 30, 2015, we did not issue or sell any shares on an unregistered basis.

Purchase of Equity Securities

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

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

None.

Item 6. Exhibits.

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

INTERCEPT PHARMACEUTICALS, INC.

Date: August 7, 2015 By: /s/ Mark Pruzanski, M.D.
Mark Pruzanski
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 7, 2015 By: /s/ Barbara Duncan
Barbara Duncan
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit Index

Exhibit Number	Description of Exhibit
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following materials from the Registrant's Quarterly Report on Form 10-Q for the period ended June 30, 2015, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheet at December 31, 2014 and June 30, 2015 (unaudited), (ii) Condensed Consolidated Statements of Operations for the three and six month periods ended June 30, 2014 and 2015 (unaudited), (iii) Condensed Consolidated Statements of Comprehensive Income (Loss) for the three and six month periods ended June 30, 2014 and 2015, (iv) Condensed Consolidated Statements of Cash Flows for the six month periods ended June 30, 2014 and 2015 (unaudited) and (v) Notes to Condensed Consolidated Financial Statements (unaudited).