

MORGAN STANLEY
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Morgan Stanley Finance LLC

Structured Investments

Opportunities in U.S. Equities

Buffered Participation Securities Based on the Value of the S&P 500[®] Index due September 28, 2023

Fully and Unconditionally Guaranteed by Morgan Stanley

Principal at Risk Securities

The Buffered Securities offered are unsecured obligations of Morgan Stanley Finance LLC (“MSFL”) and are fully and unconditionally guaranteed by Morgan Stanley. The Buffered Securities will pay no interest, provide a minimum payment at maturity of only 25% of the stated principal amount and have the terms described in the accompanying product supplement for participation securities, index supplement and prospectus, as supplemented or modified by this document. At maturity, if the underlying index has **appreciated** in value, investors will receive the stated principal amount of their investment plus a return reflecting 100% of the upside performance of the underlying index. If the underlying index has **depreciated** in value, but the underlying index has not declined by more than the specified buffer amount, the Buffered Securities will redeem for par. However, if the underlying index has declined by more than the buffer amount, investors will lose 1% for every 1% decline beyond the specified buffer amount, subject to the minimum payment at maturity of 25% of the stated principal amount. Investors may lose up to 75% of the stated principal amount of the Buffered Securities. These long-dated Buffered Securities are for investors who seek an equity index-based return and who are willing to risk their principal and forgo current income in exchange for the buffer feature that applies to a limited range of performance of the underlying index. The Buffered Securities are notes issued as part of MSFL’s Series A Global Medium-Term Notes program.

All payments are subject to our credit risk. If we default on our obligations, you could lose some or all of your investment. These Buffered Securities are not secured obligations and you will not have any security interest in, or otherwise have any access to, any underlying reference asset or assets.

Summary Terms

Issuer:	Morgan Stanley Finance LLC
Guarantor:	Morgan Stanley
Maturity date:	September 28, 2023
Underlying index:	S&P 500 [®] Index

Aggregate principal amount:	\$ If the final index value is greater than the initial index value: \$1,000 + upside payment If the final index value is less than or equal to the initial index value but has decreased from the initial index value by an amount less than or equal to the buffer amount of 25%:
Payment at maturity per Buffered Security:	\$1,000 If the final index value is less than the initial index value and has decreased from the initial index value by an amount greater than the buffer amount of 25%: (\$1,000 x the index performance factor) + \$250 <i>Under these circumstances, the payment at maturity will be less than the stated principal amount of \$1,000. However, under no circumstances will the Buffered Securities pay less than \$250 per Buffered Security at maturity.</i>
Upside payment:	\$1,000 × index percent increase
Index percent increase:	(final index value – initial index value) / initial index value
Initial index value:	, which is the index closing value on the pricing date
Final index value:	The index closing value on the valuation date
Valuation date:	September 25, 2023, subject to postponement for non-index business days and certain market disruption events
Buffer amount:	25%. As a result of the buffer amount of 25%, the value at or above which the underlying index must close on the valuation date so that investors do not suffer a loss on their initial investment in the Buffered Securities is , which is 75% of the initial index value.
Minimum payment at maturity:	\$250 per Buffered Security (25% of the stated principal amount)
Index performance factor:	Final index value <i>divided</i> by the initial index value
Stated principal amount:	\$1,000 per Buffered Security
Issue price:	\$1,000 per Buffered Security (see “Commissions and issue price” below)
Pricing date:	September 25, 2018
Original issue date:	September 28, 2018 (3 business days after the pricing date)
CUSIP:	61768DDB8
ISIN:	US61768DDB82
Listing:	The Buffered Securities will not be listed on any securities exchange.

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Agent:	Morgan Stanley & Co. LLC (“MS & Co.”), an affiliate of MSFL and a wholly owned subsidiary of Morgan Stanley. See “Supplemental information regarding plan of distribution; conflicts of interest.”		
Estimated value on the pricing date:	Approximately \$947.40 per Buffered Security, or within \$30.00 of that estimate. See “Investment Summary” beginning on page 2.		
Commissions and issue price:	Price to public ⁽¹⁾	Agent’s commissions and fees ⁽²⁾	Proceeds to us ⁽³⁾
Per Buffered Security	\$1,000	\$	\$
Total	\$	\$	\$

(1) The price to public for investors purchasing the Buffered Securities in fee-based advisory accounts will be \$970 per Buffered Security.

Selected dealers and their financial advisors will collectively receive from the agent, MS & Co., a fixed sales commission of \$ for each Buffered Security they sell; provided that dealers selling to investors purchasing the (2) Buffered Securities in fee-based advisory accounts will receive a sales commission of \$ per Buffered Security. See “Supplemental information regarding plan of distribution; conflicts of interest.” For additional information, see “Plan of Distribution (Conflicts of Interest)” in the accompanying product supplement.

(3) See “Use of proceeds and hedging” on page 11.

The Buffered Securities involve risks not associated with an investment in ordinary debt securities. See “Risk Factors” beginning on page 5.

The Securities and Exchange Commission and state securities regulators have not approved or disapproved these securities, or determined if this document or the accompanying product supplement, index supplement and prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The Buffered Securities are not deposits or savings accounts and are not insured by the Federal Deposit Insurance Corporation or any other governmental agency or instrumentality, nor are they obligations of, or guaranteed by, a bank.

You should read this document together with the related product supplement, index supplement and prospectus, each of which can be accessed via the hyperlinks below. Please also see “Additional Information About the Buffered Securities” at the end of this document.

As used in this document, “we,” “us” and “our” refer to Morgan Stanley or MSFL, or Morgan Stanley and MSFL collectively, as the context requires.

Product Supplement for Participation Securities dated November 16, 2017 **Index Supplement dated November 16, 2017**
Prospectus dated November 16, 2017

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Principal at Risk Securities

Investment Summary

Buffered Participation Securities

Principal at Risk Securities

The Buffered Participation Securities Based on the Value of the S&P 500[®] Index due September 28, 2023 (the "Buffered Securities") can be used:

§ To achieve similar levels of upside exposure to the underlying index as a direct investment

§ To obtain a buffer against a specified level of negative performance in the underlying index

Maturity: 5 years

Maximum payment at maturity: None

Buffer amount: 25%, with 1-to-1 downside exposure below the buffer

Minimum payment at maturity: \$250 per Buffered Security (25% of the stated principal amount). Investors may lose up to 75% of the stated principal amount of the Buffered Securities.

Coupon: None

The original issue price of each Buffered Security is \$1,000. This price includes costs associated with issuing, selling, structuring and hedging the Buffered Securities, which are borne by you, and, consequently, the estimated value of the Buffered Securities on the pricing date will be less than \$1,000. We estimate that the value of each Buffered Security on the pricing date will be approximately \$947.40, or within \$30.00 of that estimate. Our estimate of the value of the Buffered Securities as determined on the pricing date will be set forth in the final pricing supplement.

What goes into the estimated value on the pricing date?

In valuing the Buffered Securities on the pricing date, we take into account that the Buffered Securities comprise both a debt component and a performance-based component linked to the underlying index. The estimated value of the Buffered Securities is determined using our own pricing and valuation models, market inputs and assumptions relating to the underlying index, instruments based on the underlying index, volatility and other factors including current and expected interest rates, as well as an interest rate related to our secondary market credit spread, which is the implied interest rate at which our conventional fixed rate debt trades in the secondary market.

What determines the economic terms of the Buffered Securities?

In determining the economic terms of the Buffered Securities, including the buffer amount and the minimum payment at maturity, we use an internal funding rate, which is likely to be lower than our secondary market credit spreads and therefore advantageous to us. If the issuing, selling, structuring and hedging costs borne by you were lower or if the internal funding rate were higher, one or more of the economic terms of the Buffered Securities would be more favorable to you.

What is the relationship between the estimated value on the pricing date and the secondary market price of the Buffered Securities?

The price at which MS & Co. purchases the Buffered Securities in the secondary market, absent changes in market conditions, including those related to the underlying index, may vary from, and be lower than, the estimated value on the pricing date, because the secondary market price takes into account our secondary market credit spread as well as the bid-offer spread that MS & Co. would charge in a secondary market transaction of this type and other factors. However, because the costs associated with issuing, selling, structuring and hedging the Buffered Securities are not fully deducted upon issuance, for a period of up to 6 months following the issue date, to the extent that MS & Co. may buy or sell the Buffered Securities in the secondary market, absent changes in market conditions, including those related to the underlying index, and to our secondary market credit spreads, it would do so based on values higher than the estimated value. We expect that those higher values will also be reflected in your brokerage account statements.

MS & Co. may, but is not obligated to, make a market in the Buffered Securities, and, if it once chooses to make a market, may cease doing so at any time.

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Principal at Risk Securities

Key Investment Rationale

The Buffered Securities offer upside exposure to the underlying index while providing limited protection against negative performance of the underlying index. Once the underlying index has decreased in value by more than the specified buffer amount, investors are exposed to the negative performance of the underlying index, subject to the minimum payment at maturity. At maturity, if the underlying index has appreciated, investors will receive the stated principal amount of their investment plus a return reflecting 100% of the index percent increase. At maturity, if the underlying index has depreciated and (i) if the final index value of the underlying index has not declined from the initial index value by more than the specified buffer amount, the Buffered Securities will redeem for par, or (ii) if the final index value of the underlying index has declined by more than the buffer amount, the investor will lose 1% for every 1% decline beyond the specified buffer amount, subject to the minimum payment at maturity. **Investors may lose up to 75% of the stated principal amount of the Buffered Securities.**

Upside Scenario

The underlying index increases in value, and, at maturity, the Buffered Securities redeem for the stated principal amount of \$1,000 plus a return reflecting 100% of the index percent increase.

Par Scenario

The underlying index declines in value by no more than 25%, and, at maturity, the Buffered Securities redeem for the stated principal amount of \$1,000.

Downside Scenario

The underlying index declines in value by more than 25%, and, at maturity, the Buffered Securities redeem for less than the stated principal amount by an amount that is proportionate to the percentage decrease of the underlying index from the initial index value, plus the buffer amount of 25%. (Example: if the underlying index decreases in value by 35%, the Buffered Securities will redeem for \$900.00, or 90.00% of the stated principal amount.) The minimum payment at maturity is \$250 per Buffered Security.

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Principal at Risk Securities

How the Buffered Securities Work

Payoff Diagram

The payoff diagram below illustrates the payment at maturity on the Buffered Securities based on the following terms:

Stated principal amount:	\$1,000 per Buffered Security
Buffer amount:	25%
Maximum payment at maturity:	None
Minimum payment at maturity:	\$250 per Buffered Security

Buffered Securities Payoff Diagram

How it works

Upside Scenario. If the final index value is greater than the initial index value, investors will receive the \$1,000 § stated principal amount *plus* 100% of the appreciation of the underlying index over the term of the Buffered Securities.

§ If the underlying index appreciates 2%, investors will receive a 2% return, or \$1,020 per Buffered Security.

Par Scenario. If the final index value is less than or equal to the initial index value but has decreased from the initial § index value by an amount less than or equal to the buffer amount of 25%, investors will receive the stated principal amount of \$1,000 per Buffered Security.

§ If the underlying index depreciates 5%, investors will receive the \$1,000 stated principal amount.

§

Downside Scenario. If the final index value is less than the initial index value and has decreased from the initial index value by an amount greater than the buffer amount of 25%, investors will receive an amount that is less than the stated principal amount by an amount that is proportionate to the percentage decrease of the value of the underlying index from the initial index value, plus the buffer amount of 25%. The minimum payment at maturity is \$250 per Buffered Security.

§ For example, if the underlying index depreciates 45%, investors would lose 20.00% of their principal and receive only \$800 per Buffered Security at maturity, or 80.00% of the stated principal amount.

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Principal at Risk Securities

Risk Factors

The following is a non-exhaustive list of certain key risk factors for investors in the Buffered Securities. For further discussion of these and other risks, you should read the section entitled “Risk Factors” in the accompanying product supplement for Securities, index supplement and prospectus. We also urge you to consult your investment, legal, tax, accounting and other advisers in connection with your investment in the Buffered Securities.

Buffered Securities do not pay interest and provide a minimum payment at maturity of only 25% of your principal. The terms of the Buffered Securities differ from those of ordinary debt securities in that the Buffered Securities do not pay interest, and provide a minimum payment at maturity of only 25% of the stated principal amount of the Buffered Securities, subject to our credit risk. If the final index value is less than 75% of the initial § index value, you will receive for each Buffered Security that you hold a payment at maturity that is less than the stated principal amount of each Buffered Security by an amount proportionate to the decline in the closing value of the underlying index from the initial index value, plus \$250 per Buffered Security. **Accordingly, investors may lose up to 75% of the stated principal amount of the Buffered Securities.**

The market price of the Buffered Securities will be influenced by many unpredictable factors. Several factors, many of which are beyond our control, will influence the value of the Buffered Securities in the secondary market and the price at which MS & Co. may be willing to purchase or sell the Buffered Securities in the secondary market, including the value, volatility (frequency and magnitude of changes in value) and dividend yield of the underlying index, interest and yield rates in the market, time remaining until the Buffered Securities mature, geopolitical § conditions and economic, financial, political, regulatory or judicial events that affect the underlying index or equities markets generally and which may affect the final index value of the underlying index and any actual or anticipated changes in our credit ratings or credit spreads. Generally, the longer the time remaining to maturity, the more the market price of the Buffered Securities will be affected by the other factors described above. The value of the underlying index may be, and has recently been, volatile, and we can give you no assurance that the volatility will lessen. See “S&P 500® Index Overview” below. You may receive less, and possibly significantly less, than the stated principal amount per Buffered Security if you try to sell your Buffered Securities prior to maturity.

§ The Buffered Securities are subject to our credit risk, and any actual or anticipated changes to our credit ratings or credit spreads may adversely affect the market value of the Buffered Securities. You are dependent on our ability to pay all amounts due on the Buffered Securities at maturity and therefore you are subject to our credit risk. If we default on our obligations under the Buffered Securities, your investment would be at risk and you could lose some or all of your investment. As a result, the market value of the Buffered Securities prior to maturity will be affected by changes in the market’s view of our creditworthiness. Any actual or anticipated decline in our

credit ratings or increase in the credit spreads charged by the market for taking our credit risk is likely to adversely affect the market value of the Buffered Securities.

As a finance subsidiary, MSFL has no independent operations and will have no independent assets. As a finance subsidiary, MSFL has no independent operations beyond the issuance and administration of its securities and will have no independent assets available for distributions to holders of MSFL securities if they make claims in respect of such securities in a bankruptcy, resolution or similar proceeding. Accordingly, any recoveries by such holders will be limited to those available under the related guarantee by Morgan Stanley and that guarantee will rank § *pari passu* with all other unsecured, unsubordinated obligations of Morgan Stanley. Holders will have recourse only to a single claim against Morgan Stanley and its assets under the guarantee. Holders of securities issued by MSFL should accordingly assume that in any such proceedings they would not have any priority over and should be treated *pari passu* with the claims of other unsecured, unsubordinated creditors of Morgan Stanley, including holders of Morgan Stanley-issued securities.

The amount payable on the Buffered Securities is not linked to the value of the underlying index at any time other than the valuation date. The final index value will be based on the index closing value on the valuation date, subject to postponement for non-index business days and certain market disruption events. Even if the value of the underlying index appreciates prior to the valuation date but then drops by the valuation date by more than 25% of the § initial index value, the payment at maturity will be less, and may be significantly less, than it would have been had the payment at maturity been linked to the value of the underlying index prior to such drop. Although the actual value of the underlying index on the stated maturity date or at other times during the term of the Buffered Securities may be higher than the index closing value on the valuation date, the payment at maturity will be based solely on the index closing value on the valuation date.

Investing in the Buffered Securities is not equivalent to investing in the underlying index. Investing in the § Buffered Securities is not equivalent to investing in the underlying index or its component stocks. As an investor in the Buffered Securities, you will not have voting rights or rights to receive dividends or other distributions or any other rights with respect to stocks that constitute the underlying index.

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The rate we are willing to pay for securities of this type, maturity and issuance size is likely to be lower than the rate implied by our secondary market credit spreads and advantageous to us. Both the lower rate and the inclusion of costs associated with issuing, selling, structuring and hedging the Buffered Securities in the original issue price reduce the economic terms of the Buffered Securities, cause the estimated value of the Buffered Securities to be less than the original issue price and will adversely affect secondary market prices.

§ Assuming no change in market conditions or any other relevant factors, the prices, if any, at which dealers, including MS & Co., may be willing to purchase the Buffered Securities in secondary market transactions will likely be significantly lower than the original issue price, because secondary market prices will exclude the issuing, selling, structuring and hedging-related costs that are included in the original issue price and borne by you and because the secondary market prices will reflect our secondary market credit spreads and the bid-offer spread that any dealer would charge in a secondary market transaction of this type as well as other factors.

The inclusion of the costs of issuing, selling, structuring and hedging the Buffered Securities in the original issue price and the lower rate we are willing to pay as issuer make the economic terms of the Buffered Securities less favorable to you than they otherwise would be.

However, because the costs associated with issuing, selling, structuring and hedging the Buffered Securities are not fully deducted upon issuance, for a period of up to 6 months following the issue date, to the extent that MS & Co. may buy or sell the Buffered Securities in the secondary market, absent changes in market conditions, including those related to the underlying index, and to our secondary market credit spreads, it would do so based on values higher than the estimated value, and we expect that those higher values will also be reflected in your brokerage account statements.

Adjustments to the underlying index could adversely affect the value of the Buffered Securities. The underlying index publisher may add, delete or substitute the stocks constituting the underlying index or make other methodological changes that could change the value of the underlying index. The underlying index publisher may discontinue or suspend calculation or publication of the underlying index at any time. In these circumstances, the calculation agent will have the sole discretion to substitute a successor index that is comparable to the discontinued § underlying index and is not precluded from considering indices that are calculated and published by the calculation agent or any of its affiliates. If the calculation agent determines that there is no appropriate successor index, the payment at maturity on the Buffered Securities will be an amount based on the closing prices at maturity of the securities composing the underlying index at the time of such discontinuance, without rebalancing or substitution, computed by the calculation agent in accordance with the formula for calculating the underlying index last in effect prior to discontinuance of the underlying index.

The estimated value of the Buffered Securities is determined by reference to our pricing and valuation models, which may differ from those of other dealers and is not a maximum or minimum secondary market price. These pricing and valuation models are proprietary and rely in part on subjective views of certain market inputs and certain assumptions about future events, which may prove to be incorrect. As a result, because there is no market-standard way to value these types of securities, our models may yield a higher estimated value of the Buffered Securities than those generated by others, including other dealers in the market, if they attempted to value the Buffered Securities. In addition, the estimated value on the pricing date does not represent a minimum or maximum price at which dealers, including MS & Co., would be willing to purchase your Buffered Securities in the secondary market (if any exists) at any time. The value of your Buffered Securities at any time after the date of this document will vary based on many factors that cannot be predicted with accuracy, including our creditworthiness and changes in market conditions. See also “The market price of the Buffered Securities will be influenced by many unpredictable factors” above.

The Buffered Securities will not be listed on any securities exchange and secondary trading may be limited. The Buffered Securities will not be listed on any securities exchange. Therefore, there may be little or no secondary market for the Buffered Securities. MS & Co. may, but is not obligated to, make a market in the Buffered Securities and, if it once chooses to make a market, may cease doing so at any time. When it does make a market, it will generally do so for transactions of routine secondary market size at prices based on its estimate of the current value of the Buffered Securities, taking into account its bid/offer spread, our credit spreads, market volatility, the notional size of the proposed sale, the cost of unwinding any related hedging positions, the time remaining to maturity and the likelihood that it will be able to resell the Buffered Securities. Even if there is a secondary market, it may not provide enough liquidity to allow you to trade or sell the Buffered Securities easily. Since other broker-dealers may not participate significantly in the secondary market for the Buffered Securities, the price at which you may be able to trade your Buffered Securities is likely to depend on the price, if any, at which MS & Co. is willing to transact. If, at any time, MS & Co. were to cease making a market in the Buffered Securities, it is likely that there would be no secondary market for the Buffered Securities. Accordingly, you should be willing to hold your Buffered Securities to maturity.

The calculation agent, which is a subsidiary of Morgan Stanley and an affiliate of MSFL, will make determinations with respect to the Buffered Securities. As calculation agent, MS & Co. will determine the initial index value and the final index value, and will calculate the amount of cash you receive at maturity. Moreover, certain determinations made by MS & Co., in its

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capacity as calculation agent, may require it to exercise discretion and make subjective judgments, such as with respect to the occurrence or non-occurrence of market disruption events and the selection of a successor index or calculation of the final index value in the event of a market disruption event or discontinuance of the underlying index. These potentially subjective determinations may adversely affect the payout to you at maturity. For further information regarding these types of determinations, see “Description of Participation Securities—Postponement of Valuation Date(s)” and “—Calculation Agent and Calculations” and related definitions in the accompanying product supplement. In addition, MS & Co. has determined the estimated value of the Buffered Securities on the pricing date.

Hedging and trading activity by our affiliates could potentially adversely affect the value of the Buffered Securities. One or more of our affiliates and/or third-party dealers expect to carry out hedging activities related to the Buffered Securities (and possibly to other instruments linked to the underlying index or its component stocks), including trading in the stocks that constitute the underlying index as well as in other instruments related to the underlying index. As a result, these entities may be unwinding or adjusting hedge positions during the term of the Buffered Securities, and the hedging strategy may involve greater and more frequent dynamic adjustments to the hedge as the valuation date approaches. Some of our affiliates also trade the stocks that constitute the underlying § index and other financial instruments related to the underlying index on a regular basis as part of their general broker-dealer and other businesses. Any of these hedging or trading activities on or prior to the pricing date could potentially increase the initial index value, and, therefore, could increase the value at or above which the underlying index must close on the valuation date so that investors do not suffer a loss on their initial investment in the Buffered Securities. Additionally, such hedging or trading activities during the term of the Buffered Securities, including on the valuation date, could adversely affect the closing value of the underlying index on the valuation date, and, accordingly, the amount of cash an investor will receive at maturity.

§ **The U.S. federal income tax consequences of an investment in the Buffered Securities are uncertain.** Please read the discussion under “Additional provisions—Tax considerations” in this document and the discussion under “United States Federal Taxation” in the accompanying product supplement for participation securities (together, the “Tax Disclosure Sections”) concerning the U.S. federal income tax consequences of an investment in the Buffered Securities. If the Internal Revenue Service (the “IRS”) were successful in asserting an alternative treatment, the timing and character of income on the Buffered Securities might differ significantly from the tax treatment described in the Tax Disclosure Sections. For example, under one possible treatment, the IRS could seek to recharacterize the Buffered Securities as debt instruments. In that event, U.S. Holders would be required to accrue into income original issue discount on the Buffered Securities every year at a “comparable yield” determined at the time of issuance and recognize all income and gain in respect of the Buffered Securities as ordinary income. Additionally, as discussed under “United States Federal Taxation—FATCA” in the accompanying product supplement for participation securities, the withholding rules commonly referred to as “FATCA” would apply to the Buffered Securities if they were recharacterized as debt instruments. The risk that financial instruments providing for buffers, triggers or similar downside protection features, such as the Buffered Securities, would be recharacterized as debt is greater than the risk of recharacterization for comparable financial instruments that do not have such features. We do not plan to

request a ruling from the IRS regarding the tax treatment of the Buffered Securities, and the IRS or a court may not agree with the tax treatment described in the Tax Disclosure Sections.

In 2007, the U.S. Treasury Department and the IRS released a notice requesting comments on the U.S. federal income tax treatment of “prepaid forward contracts” and similar instruments. The notice focuses in particular on whether to require holders of these instruments to accrue income over the term of their investment. It also asks for comments on a number of related topics, including the character of income or loss with respect to these instruments; whether short-term instruments should be subject to any such accrual regime; the relevance of factors such as the exchange-traded status of the instruments and the nature of the underlying property to which the instruments are linked; the degree, if any, to which income (including any mandated accruals) realized by non-U.S. investors should be subject to withholding tax; and whether these instruments are or should be subject to the “constructive ownership” rule, which very generally can operate to recharacterize certain long-term capital gain as ordinary income and impose an interest charge. While the notice requests comments on appropriate transition rules and effective dates, any Treasury regulations or other guidance promulgated after consideration of these issues could materially and adversely affect the tax consequences of an investment in the Buffered Securities, possibly with retroactive effect. Both U.S. and Non-U.S. Holders should consult their tax advisers regarding the U.S. federal income tax consequences of an investment in the Buffered Securities, including possible alternative treatments, the issues presented by this notice and any tax consequences arising under the laws of any state, local or non-U.S. taxing jurisdiction.

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S&P 500® Index Overview

The S&P 500® Index, which is calculated, maintained and published by S&P Dow Jones Indices LLC (“S&P”), consists of stocks of 500 component companies selected to provide a performance benchmark for the U.S. equity markets. The calculation of the S&P 500® Index is based on the relative value of the float adjusted aggregate market capitalization of the 500 component companies as of a particular time as compared to the aggregate average market capitalization of 500 similar companies during the base period of the years 1941 through 1943. For additional information about the S&P 500® Index, see the information set forth under “S&P 500® Index” in the accompanying index supplement.

Information as of market close on August 31, 2018:

Bloomberg Ticker Symbol:	SPX
Current Index Value:	2,901.52
52 Weeks Ago:	2,471.65
52 Week High (on 8/29/2018):	2,914.04
52 Week Low (on 9/5/2017):	2,457.85

The following graph sets forth the daily index closing values of the underlying index for each quarter in the period from January 1, 2013 through August 31, 2018. The related table sets forth the published high and low closing values, as well as end-of-quarter closing values, of the underlying index for each quarter in the same period. The index closing value of the underlying index on August 31, 2018 was 2,901.52. We obtained the information in the table and graph below from Bloomberg Financial Markets, without independent verification. The underlying index has at times experienced periods of high volatility. You should not take the historical values of the underlying index as an indication of its future performance, and no assurance can be given as to the index closing value of the underlying index on the valuation date.

S&P 500® Index Daily Index Closing Values

January 1, 2013 to August 31, 2018

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S&P 500® Index	High	Low	Period End
2013			
First Quarter	1,569.19	1,457.15	1,569.19
Second Quarter	1,669.16	1,541.61	1,606.28
Third Quarter	1,725.52	1,614.08	1,681.55
Fourth Quarter	1,848.36	1,655.45	1,848.36
2014			
First Quarter	1,878.04	1,741.89	1,872.34
Second Quarter	1,962.87	1,815.69	1,960.23
Third Quarter	2,011.36	1,909.57	1,972.29
Fourth Quarter	2,090.57	1,862.49	2,058.90
2015			
First Quarter	2,117.39	1,992.67	2,067.89
Second Quarter	2,130.82	2,057.64	2,063.11
Third Quarter	2,128.28	1,867.61	1,920.03
Fourth Quarter	2,109.79	1,923.82	2,043.94
2016			
First Quarter	2,063.95	1,829.08	2,059.74
Second Quarter	2,119.12	2,000.54	2,098.86
Third Quarter	2,190.15	2,088.55	2,168.27
Fourth Quarter	2,271.72	2,085.18	2,238.83
2017			
First Quarter	2,395.96	2,257.83	2,362.72
Second Quarter	2,453.46	2,328.95	2,423.41
Third Quarter	2,519.36	2,409.75	2,519.36
Fourth Quarter	2,690.16	2,529.12	2,673.61
2018			
First Quarter	2,872.87	2,581.00	2,640.87
Second Quarter	2,786.85	2,581.88	2,718.37
Third Quarter (through August 31, 2018)	2,914.04	2,713.22	2,901.52

“Standard & Poor®,” “S&P,” “S&P 500” “Standard & Poor’s 500” and “500” are trademarks of Standard and Poor’s Financial Services LLC. See “S&P 500® Index” in the accompanying index supplement.

Morgan Stanley Finance LLC

Buffered Participation Securities Based on the Value of the S&P 500® Index due September 28, 2023

Principal at Risk Securities

Additional Information About the Buffered Securities

Please read this information in conjunction with the summary terms on the front cover of this document.

Additional

Provisions:

Underlying index publisher: S&P Dow Jones Indices LLC

Interest: None

Bull market or bear market securities: Bull market securities

Postponement of maturity date: If the scheduled valuation date is not an index business day or if a market disruption event occurs on that day so that the valuation date as postponed falls less than two business days prior to the scheduled maturity date, the maturity date of the Buffered Securities will be postponed to the second business day following that valuation date as postponed.

Denominations: \$1,000 per Buffered Security and integral multiples thereof

Minimum ticketing size: \$1,000 / 1 Buffered Security

Tax considerations: Although there is uncertainty regarding the U.S. federal income tax consequences of an investment in the Buffered Securities due to the lack of governing authority, in the opinion of our counsel, Davis Polk & Wardwell LLP, under current law, and based on current market conditions, a Buffered Security should be treated as a single financial contract that is an “open transaction” for U.S. federal income tax purposes.

Assuming this treatment of the Buffered Securities is respected and subject to the discussion in “United States Federal Taxation” in the accompanying product supplement for participation securities, the following U.S. federal income tax consequences should result based on current law:

§ A U.S. Holder should not be required to recognize taxable income over the term of the Buffered Securities prior to settlement, other than pursuant to a sale or exchange.

§ Upon sale, exchange or settlement of the Buffered Securities, a U.S. Holder should recognize gain or loss equal to the difference between the amount realized and the U.S. Holder's tax basis in the Buffered Securities. Such gain or loss should be long-term capital gain or loss if the investor has held the Buffered Securities for more than one year, and short-term capital gain or loss otherwise.

In 2007, the U.S. Treasury Department and the Internal Revenue Service (the "IRS") released a notice requesting comments on the U.S. federal income tax treatment of "prepaid forward contracts" and similar instruments. The notice focuses in particular on whether to require holders of these instruments to accrue income over the term of their investment. It also asks for comments on a number of related topics, including the character of income or loss with respect to these instruments; whether short-term instruments should be subject to any such accrual regime; the relevance of factors such as the exchange-traded status of the instruments and the nature of the underlying property to which the instruments are linked; the degree, if any, to which income (including any mandated accruals) realized by non-U.S. investors should be subject to withholding tax; and whether these instruments are or should be subject to the "constructive ownership" rule, which very generally can operate to recharacterize certain long-term capital gain as ordinary income and impose an interest charge. While the notice requests comments on appropriate transition rules and effective dates, any Treasury regulations or other guidance promulgated after consideration of these issues could materially and adversely affect the tax consequences of an investment in the Buffered Securities, possibly with retroactive effect.

As discussed in the accompanying product supplement for participation securities, Section 871(m) of the Internal Revenue Code of 1986, as amended, and Treasury regulations promulgated thereunder ("Section 871(m)") generally impose a 30% (or a lower applicable treaty rate) withholding tax on dividend equivalents paid or deemed paid to Non-U.S. Holders with respect to certain financial instruments linked to U.S. equities or indices that include U.S. equities (each, an "Underlying Security"). Subject to certain exceptions, Section 871(m) generally applies to securities that substantially replicate the economic performance of one or more Underlying Securities, as determined based on tests set forth in the applicable Treasury regulations (a "Specified Security"). However, pursuant to an IRS notice, Section 871(m) will not apply to securities issued before January 1, 2019 that do not have a delta of one with respect to any Underlying Security. Based on our determination that the Buffered Securities do not have a delta of one with respect to any Underlying Security, our counsel is of the opinion that the Buffered Securities should not be Specified Securities and, therefore, should not be subject to Section 871(m).

Our determination is not binding on the IRS, and the IRS may disagree with this determination. Section 871(m) is complex and its application may depend on your particular circumstances, including whether you enter into other transactions with respect to an Underlying Security. If withholding is required, we will not be required to pay any additional amounts with respect to the amounts so withheld. You should consult your tax adviser regarding the potential application of Section 871(m) to the Buffered Securities.

Both U.S. and non-U.S. investors considering an investment in the Buffered Securities should read the discussion under “Risk Factors” in this document and the discussion under “United States Federal

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Taxation” in the accompanying product supplement for participation securities and consult their tax advisers regarding all aspects of the U.S. federal income tax consequences of an investment in the Buffered Securities, including possible alternative treatments, the issues presented by the aforementioned notice and any tax consequences arising under the laws of any state, local or non-U.S. taxing jurisdiction.

The discussion in the preceding paragraphs under “Tax considerations” and the discussion contained in the section entitled “United States Federal Taxation” in the accompanying product supplement for participation securities, insofar as they purport to describe provisions of U.S. federal income tax laws or legal conclusions with respect thereto, constitute the full opinion of Davis Polk & Wardwell LLP regarding the material U.S. federal tax consequences of an investment in the Buffered Securities.

Trustee: The Bank of New York Mellon

Calculation agent: MS & Co.

Use of proceeds and hedging: The proceeds from the sale of the Buffered Securities will be used by us for general corporate purposes. We will receive, in aggregate, \$1,000 per Buffered Security issued, because, when we enter into hedging transactions in order to meet our obligations under the Buffered Securities, our hedging counterparty will reimburse the cost of the agent’s commissions. The costs of the Buffered Securities borne by you and described beginning on page 2 above comprise the agent’s commissions and the cost of issuing, structuring and hedging the Buffered Securities.

On or prior to the pricing date, we will hedge our anticipated exposure in connection with the Buffered Securities by entering into hedging transactions with our affiliates and/or third party dealers. We expect our hedging counterparties to take positions in stocks of the underlying index, futures and options contracts on the underlying index and any component stocks of the underlying index listed on major securities markets or positions in any other available securities or instruments that they may wish to use in connection with such hedging. Such purchase activity could potentially increase the value of the underlying index on the pricing date, and, therefore, could increase the value at or above which the underlying index must close on the valuation date so that investors do not suffer a loss on their initial investment in the Buffered Securities. In addition, through our affiliates, we are likely to modify our hedge position throughout the term of the Buffered Securities, including on the valuation date, by purchasing and selling the stocks constituting the underlying index, futures or options contracts on the underlying index or its component stocks listed on major securities markets or positions in any other available securities or instruments that we may wish to use in connection with such hedging activities. As a result, these entities may be unwinding or adjusting hedge positions during the term of the Buffered Securities, and the hedging strategy may

involve greater and more frequent dynamic adjustments to the hedge as the valuation date approaches. We cannot give any assurance that our hedging activities will not affect the value of the underlying index, and, therefore, adversely affect the value of the Buffered Securities or the payment you will receive at maturity. For further information on our use of proceeds and hedging, see “Use of Proceeds and Hedging” in the accompanying product supplement for participation securities.

Each fiduciary of a pension, profit-sharing or other employee benefit plan subject to Title I of the Employee Retirement Income Security Act of 1974, as amended (“ERISA”) (a “Plan”), should consider the fiduciary standards of ERISA in the context of the Plan’s particular circumstances before authorizing an investment in the Buffered Securities. Accordingly, among other factors, the fiduciary should consider whether the investment would satisfy the prudence and diversification requirements of ERISA and would be consistent with the documents and instruments governing the Plan.

**Benefit plan
investor
considerations:**

In addition, we and certain of our affiliates, including MS & Co., may each be considered a “party in interest” within the meaning of ERISA, or a “disqualified person” within the meaning of the Internal Revenue Code of 1986, as amended (the “Code”), with respect to many Plans, as well as many individual retirement accounts and Keogh plans (such accounts and plans, together with other plans, accounts and arrangements subject to Section 4975 of the Code, also “Plans”). ERISA Section 406 and Section 4975 of the Code generally prohibit transactions between Plans and parties in interest or disqualified persons. Prohibited transactions within the meaning of ERISA or the Code would likely arise, for example, if the Buffered Securities are acquired by or with the assets of a Plan with respect to which MS & Co. or any of its affiliates is a service provider or other party in interest, unless the Buffered Securities are acquired pursuant to an exemption from the “prohibited transaction” rules. A violation of these “prohibited transaction” rules could result in an excise tax or other liabilities under ERISA and/or Section 4975 of the Code for those persons, unless exemptive relief is available under an applicable statutory or administrative exemption.

The U.S. Department of Labor has issued five prohibited transaction class exemptions (“PTCEs”) that may provide exemptive relief for direct or indirect prohibited transactions resulting from the purchase or holding of the Buffered Securities. Those class exemptions are PTCE 96-23 (for certain transactions determined by in-house asset managers), PTCE 95-60 (for certain transactions involving insurance company general accounts), PTCE 91-38 (for certain transactions involving bank collective investment funds), PTCE 90-1 (for certain transactions involving insurance company separate accounts) and PTCE 84-14 (for certain transactions determined by independent qualified professional asset managers). In addition, ERISA Section 408(b)(17) and Section 4975(d)(20) of the Code provide an exemption for the purchase and sale of securities and the related lending transactions, provided that neither the issuer of the securities nor any of its affiliates has or exercises any discretionary authority or control or renders any investment advice with respect to the assets of the Plan involved in the transaction and provided further that the Plan pays no more, and receives no less, than

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“adequate consideration” in connection with the transaction (the so-called “service provider” exemption). There can be no assurance that any of these class or statutory exemptions will be available with respect to transactions involving the Buffered Securities.

Because we may be considered a party in interest with respect to many Plans, the Buffered Securities may not be purchased, held or disposed of by any Plan, any entity whose underlying assets include “plan assets” by reason of any Plan’s investment in the entity (a “Plan Asset Entity”) or any person investing “plan assets” of any Plan, unless such purchase, holding or disposition is eligible for exemptive relief, including relief available under PTCEs 96-23, 95-60, 91-38, 90-1, 84-14 or the service provider exemption or such purchase, holding or disposition is otherwise not prohibited. Any purchaser, including any fiduciary purchasing on behalf of a Plan, transferee or holder of the Buffered Securities will be deemed to have represented, in its corporate and its fiduciary capacity, by its purchase and holding of the Buffered Securities that either (a) it is not a Plan or a Plan Asset Entity and is not purchasing such Buffered Securities on behalf of or with “plan assets” of any Plan or with any assets of a governmental, non-U.S. or church plan that is subject to any federal, state, local or non-U.S. law that is substantially similar to the provisions of Section 406 of ERISA or Section 4975 of the Code (“Similar Law”) or (b) its purchase, holding and disposition of these Buffered Securities will not constitute or result in a non-exempt prohibited transaction under Section 406 of ERISA or Section 4975 of the Code or violate any Similar Law.

Due to the complexity of these rules and the penalties that may be imposed upon persons involved in non-exempt prohibited transactions, it is particularly important that fiduciaries or other persons considering purchasing the Buffered Securities on behalf of or with “plan assets” of any Plan consult with their counsel regarding the availability of exemptive relief.

The Buffered Securities are contractual financial instruments. The financial exposure provided by the Buffered Securities is not a substitute or proxy for, and is not intended as a substitute or proxy for, individualized investment management or advice for the benefit of any purchaser or holder of the Buffered Securities. The Buffered Securities have not been designed and will not be administered in a manner intended to reflect the individualized needs and objectives of any purchaser or holder of the Buffered Securities.

Each purchaser or holder of any Buffered Securities acknowledges and agrees that:

(i) the purchaser or holder or its fiduciary has made and shall make all investment decisions for the purchaser or holder and the purchaser or holder has not relied and shall not rely in any way upon us or our affiliates to act as a fiduciary or adviser of the purchaser or holder with respect to (A) the design and terms of the Buffered Securities, (B) the purchaser or holder's investment in the Buffered Securities, or (C) the exercise of or failure to exercise any rights we have under or with respect to the Buffered Securities;

(ii) we and our affiliates have acted and will act solely for our own account in connection with (A) all transactions relating to the Buffered Securities and (B) all hedging transactions in connection with our obligations under the Buffered Securities;

(iii) any and all assets and positions relating to hedging transactions by us or our affiliates are assets and positions of those entities and are not assets and positions held for the benefit of the purchaser or holder;

(iv) our interests are adverse to the interests of the purchaser or holder; and

(v) neither we nor any of our affiliates is a fiduciary or adviser of the purchaser or holder in connection with any such assets, positions or transactions, and any information that we or any of our affiliates may provide is not intended to be impartial investment advice.

Each purchaser and holder of the Buffered Securities has exclusive responsibility for ensuring that its purchase, holding and disposition of the Buffered Securities do not violate the prohibited transaction rules of ERISA or the Code or any Similar Law. The sale of any Buffered Securities to any Plan or plan subject to Similar Law is in no respect a representation by us or any of our affiliates or representatives that such an investment meets all relevant legal requirements with respect to investments by plans generally or any particular plan, or that such an investment is appropriate for plans generally or any particular plan. In this regard, neither this discussion nor anything provided in this document is or is intended to be investment advice directed at any potential Plan purchaser or at Plan purchasers generally and such purchasers of the Buffered Securities should consult and rely on their own counsel and advisers as to whether an investment in the Buffered Securities is suitable.

However, individual retirement accounts, individual retirement annuities and Keogh plans, as well as employee benefit plans that permit participants to direct the investment of their accounts, will not be permitted to purchase or hold the Buffered Securities if the account, plan or annuity is for the benefit of an employee of Morgan Stanley or Morgan Stanley Wealth Management or a

Additional considerations:

family member and the employee receives any compensation (such as, for example, an addition to bonus) based on the purchase of the Buffered Securities by the account, plan or annuity. Client accounts over which Morgan Stanley, Morgan Stanley Wealth Management or any of their respective subsidiaries have investment discretion are not permitted to purchase the Buffered Securities, either directly or indirectly.

Supplemental information regarding plan of distribution; conflicts of interest:

Selected dealers, which may include our affiliates, and their financial advisors will collectively receive from the agent a fixed sales commission of \$ for each Buffered Security they sell; *provided* that dealers selling to investors purchasing the Buffered Securities in fee-based advisory accounts will receive a sales commission of \$

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	2016	2015
Work in process	\$2,232	\$1,612
Inventories	\$2,232	\$1,612

Property and Equipment

Property and equipment are recorded at cost. Depreciation is computed using the straight-line method over the estimated useful lives of the assets. Computer equipment is depreciated over a life of three years. Laboratory equipment, office equipment, and software are depreciated over a life of five years. Furniture and fixtures are depreciated over a life of seven years. Leasehold improvements are amortized over their estimated useful lives or the expected lease term, whichever is less. Property consists of a leased building which did not meet the sale-leaseback criteria and is recorded at its fair value, less depreciation. The building is being depreciated over a period equal to the expected term of the related lease.

In accordance with U.S. GAAP, the Company periodically reviews its property and equipment for impairment when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written down to their estimated fair values. Property and equipment to be disposed of are reported at the lower of carrying amount or fair value less cost to sell.

Patents and Licenses

The Company seeks patent protection on all internally developed processes and products. All patent related costs are expensed to selling, general and administrative expenses when incurred as recoverability of such expenditures is uncertain.

Accrued Expenses

The Company generally enters into contractual agreements with third-party vendors who provide research and development, manufacturing, and other services in the ordinary course of business. Some of these contracts are subject to milestone-based invoicing and services are completed over an extended period of time. The Company records liabilities under these contractual commitments when it determines an obligation has been incurred, regardless of the timing of the invoice. This process involves reviewing open contracts and purchase orders, communicating with applicable Company personnel to identify services that have been performed on its behalf and estimating the level of service performed and the associated cost incurred for the service when the Company has not yet been invoiced or otherwise notified of actual cost. The majority of service providers invoice the Company monthly in arrears for services performed. The Company makes estimates of accrued expenses as of each balance sheet date in its financial statements based on the facts and circumstances. The Company periodically confirms the accuracy of its estimates with the service providers and makes adjustments if necessary. Examples of estimated accrued expenses include:

- fees paid to Clinical Research Organizations (“CROs”) in connection with preclinical and toxicology studies and clinical trials;
- fees paid to investigative sites in connection with clinical trials;
- fees paid to contract manufacturers in connection with the production of our raw materials, drug substance and drug products; and
- professional fees.

The Company bases its expenses related to clinical trials on its estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials on the Company’s behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly. As of September 30, 2016 and December 31, 2015, the carrying value of accrued expenses approximates their fair value due to their short-term settlement.

Income Taxes

The liability method is used in the Company's accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse.

Accumulated Other Comprehensive Income (Loss)

Accumulated other comprehensive income (loss) is comprised of unrealized gains and losses on available-for-sale investments and is disclosed as a separate component of stockholders' equity. Amounts reclassified from accumulated other comprehensive income (loss) are recorded as interest and other income on the Consolidated Statements of Comprehensive Loss. During the nine months ended September 30, 2016, realized gains of \$11 were reclassified out of accumulated other comprehensive income (loss). During the nine months ended September 30, 2015, realized gains of \$13 were reclassified out of accumulated other comprehensive income (loss).

Revenue Recognition

The Company recognizes revenues from collaborative and other research and development arrangements, royalties and product sales when realized or realizable and earned. Revenue is realized or realizable and earned when all of the following criteria are met: (i) persuasive evidence of an arrangement exists; (ii) delivery has occurred or services have been rendered; (iii) the seller's price to the buyer is fixed or determinable; and (iv) collectability is reasonably assured.

Collaborative and Other Research and Development Arrangements and Royalties

Revenue from license fees, royalty payments, event payments, and research and development fees are recognized as revenue when the earnings process is complete and the Company has no further continuing performance obligations or the Company has completed the performance obligations under the terms of the agreement. Fees received under licensing agreements that are related to future performance are deferred and recognized over an estimated period determined by management based on the terms of the agreement and the products licensed. Revisions to revenue or profit estimates as a result of changes in the estimated revenue period are recognized prospectively.

Under certain of the Company's license agreements, the Company receives royalty payments based upon its licensees' net sales of covered products. The Company recognizes royalty revenues when it can reliably estimate such amounts and collectability is reasonably assured.

For arrangements that involve the delivery of more than one element, each product, service and/or right to use assets is evaluated to determine whether it qualifies as a separate unit of accounting. This determination is based on whether the deliverable has "stand-alone value" to the customer. The consideration that is fixed or determinable is then allocated to each separate unit of accounting based on the relative selling price of each deliverable. The estimated selling price of each deliverable is determined using the following hierarchy of values: (i) vendor-specific objective evidence of fair value, (ii) third-party evidence of selling price ("TPE") and (iii) best estimate of selling price ("BESP"). The BESP reflects our best estimate of what the selling price would be if the deliverable was regularly sold by the Company on a stand-alone basis. In most cases the Company expects to use TPE or BESP for allocating consideration to each deliverable. The consideration allocated to each unit of accounting is recognized as the related goods or services are delivered, limited to the consideration that is not contingent upon future deliverables. Analyzing the arrangement to identify deliverables requires the use of judgment, and each deliverable may be an obligation to deliver services, a right or license to use an asset, or another performance obligation.

In June 2015, the Company entered into a License Agreement (the "SUL Agreement") granting SUL and its affiliates worldwide rights, excluding Israel, Japan, Korea and Taiwan, to develop, manufacture and commercialize RAPIVAB. The SUL Agreement provides for various types of payments, including a non-refundable upfront fee, milestone payments, and future royalties. Analysis of the SUL Agreement identified three deliverables: (i) license rights, (ii) inventory and (iii) regulatory support to obtain Canadian and European Union ("EU") marketing approvals. The Company received an upfront payment of \$33,740 from SUL, of which \$7,000 was determined to be contingent upon EU marketing approval and will be deferred until that time. Approximately \$21,777 of the upfront payment was allocated to the license rights and recognized as revenue in the second quarter. Approximately \$3,740 of the upfront payment was allocated to the pending sale of inventory and was recognized during the third quarter of 2015, when the inventory transfer was completed. Approximately \$1,223 of the revenue from the SUL Agreement will be recognized over the expected period of involvement in these regulatory support activities.

Milestone payments are recognized as licensing revenue upon the achievement of specified milestones if (i) the milestone is substantive in nature and the achievement of the milestone was not reasonably assured at the inception of the agreement; and (ii) the fees are non-refundable. Any milestone payments received prior to satisfying these revenue recognition criteria are recorded as deferred revenue.

Under the terms of the SUL Agreement, the Company may receive up to \$12,000 in additional payments related to the successful achievement of regulatory milestones, including marketing approval (i) by the FDA for a pediatric indication, (ii) by the EMA for an adult indication in the EU and (iii) by Health Products and Food Branch of Health Canada (“Health Canada”) for an adult indication in Canada. The Company evaluated each event based payment under the provisions of ASU 2010-17, *Milestone Method of Revenue Recognition*, and determined that each event based payment met the criteria to be considered substantive and represents a milestone under the milestone method of accounting. No event based payments were achieved during the periods presented.

Reimbursements received for direct out-of-pocket expenses related to research and development costs are recorded as revenue in the Consolidated Statements of Comprehensive Loss rather than as a reduction in expenses. Under the Company’s contracts with the Biomedical Advanced Research and Development Authority within the United States Department of Health and Human Services (“BARDA/HHS”) and the National Institute of Allergy and Infectious Diseases (“NIAID/HHS”), revenue is recognized as reimbursable direct and indirect costs are incurred.

Product Sales

The Company recognizes revenue for sales of RAPIVAB when title and substantially all the risks and rewards of ownership have transferred to the customer, which generally occurs on the date of shipment from our specialty distributors, utilizing the Sell-Through revenue recognition methodology. Product sales are recognized when there is persuasive evidence that an arrangement exists, title has passed, the price is fixed and determinable, and collectability is reasonably assured. Product sales are recognized net of estimated allowances, discounts, sales returns, chargebacks and rebates. In the United States, and prior to the SUL Agreement, the Company sold RAPIVAB to specialty distributors, who in turn, sell to physician offices, hospitals and federal, state and commercial health care organizations. With the completion of the SUL worldwide license of RAPIVAB, SUL will be responsible for sales of RAPIVAB, other than U.S. Government stockpiling sales. With the completion of the SUL collaboration, all peramivir sales (i.e., RAPIVAB, RAPIACTA, and PERAMIFLU) will be made by the Company’s partners, except for U.S. Government stockpiling sales, and the Company will be reliant on these partners to generate sales.

Sales deductions consist of statutory rebates to state Medicaid, Medicare and other government agencies and sales discounts (including trade discounts and distribution service fees). These deductions are recorded as reductions from revenue from RAPIVAB in the same period as the related sales with estimates of future utilization derived from historical experience adjusted to reflect known changes in the factors that impact such reserves.

The Company utilizes data from external sources to help it estimate gross-to-net sales adjustments as they relate to the recognition of revenue for RAPIVAB sold. Externally sourced data includes, but is not limited to, information obtained from specialty distributors with respect to their inventory levels and their sell-through to customers, as well as information from third-party suppliers of market research data to the pharmaceutical industry.

The Company accounts for these sales deductions in accordance with authoritative guidance on revenue recognition when consideration is given by a vendor to a customer.

The Company has categorized and described more fully the following significant sales deductions, all of which involve estimates and judgments, which the Company considers to be critical accounting estimates, and require it to use information from external sources.

Rebates and Chargebacks

Statutory rebates to state Medicaid agencies and Medicare are based on statutory discounts to RAPIVAB's selling price. As it can take up to nine months or more for information to be received on actual usage of RAPIVAB in Medicaid and other governmental programs, the Company maintains reserves for amounts payable under these programs relating to RAPIVAB sales.

Chargebacks claimed by specialty distributors are based on the differentials between product acquisition prices paid by the specialty distributors and lower government contract pricing paid by eligible customers covered under federally qualified programs.

The amount of the reserve for rebates and chargebacks is based on multiple qualitative and quantitative factors, including the historical and projected utilization levels, historical payment experience, changes in statutory laws and interpretations as well as contractual terms, product pricing (both normal selling prices and statutory or negotiated prices), changes in prescription demand patterns and utilization of the Company's product through public benefit plans, and the levels of RAPIVAB inventory in the distribution channel. The Company acquires prescription utilization data from third-party suppliers of market research data to the pharmaceutical industry. The Company updates its estimates and assumptions each period and records any necessary adjustments to its reserves. Settlements of rebates and chargebacks typically occur within nine months from point of sale. To the extent actual rebates and chargebacks differ from the Company's estimates, additional reserves may be required or reserves may need to be reversed, either of which would impact current period product revenue.

Discounts and Sales Incentives

Discounts and other sales incentives primarily consist of Inventory Management Agreement (“IMA”) fees. Per contractual agreements with the Company’s specialty distributors, the Company provides an IMA fee based on a percentage of their purchases of RAPIVAB. The IMA fee rates are set forth in individual contracts. The Company tracks sales to these distributors each period and accrues a liability relating to the unpaid portion of these fees by applying the contractual rates to such product sales. With the completion of the SUL collaboration, all peramivir sales (i.e., RAPIVAB, RAPIACTA, and PERAMIFLU) will be made by the Company’s partners, except for U.S. Government stockpiling sales, and the Company will be reliant on these partners to generate sales and to provide for discounts and sales incentives.

Product Returns

The Company does not record a product return allowance as it does not offer the ability to return goods once a bonafide shipment has been accepted by a specialty distributor.

The Company recorded the following revenues for the three and nine months ended September 30, 2016 and 2015:

	Three Months		Nine Months	
	2016	2015	2016	2015
Product sales, net	\$—	\$5,699	\$—	\$6,236
Royalty revenue	3,501	126	6,020	1,776
Collaborative and other research and development revenues:				
U.S. Department of Health and Human Services	3,813	4,582	9,846	12,788
Green Cross Corporation	—	132	—	132
Shionogi (Japan)	296	296	888	888
Seqirus UK Limited	153	152	616	21,835
Total collaborative and other research and development revenues	4,262	5,162	11,350	35,643
Total revenues	\$7,763	\$10,987	\$17,370	\$43,655

Advertising

The Company engages in very limited distribution and direct-response advertising when promoting RAPIVAB. Advertising and promotional costs are expensed as the costs are incurred.

Research and Development Expenses

The Company's research and development costs are charged to expense when incurred. Research and development expenses include all direct and indirect development costs related to the development of the Company's portfolio of product candidates. Advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts are recognized as expense when the related goods are delivered or the related services are performed. Research and development expenses include, among other items, personnel costs, including salaries and benefits, manufacturing costs, clinical, regulatory, and toxicology services performed by CROs, materials and supplies, and overhead allocations consisting of various administrative and facilities related costs. Most of the Company's manufacturing and clinical and preclinical studies are performed by third-party CROs. Costs for studies performed by CROs are accrued by the Company over the service periods specified in the contracts and estimates are adjusted, if required, based upon the Company's on-going review of the level of services actually performed.

Additionally, the Company has license agreements with third parties, such as Albert Einstein College of Medicine of Yeshiva University ("AECOM"), Industrial Research, Ltd. ("IRL"), and the University of Alabama at Birmingham ("UAB"), which require fees related to sublicense agreements or maintenance fees. The Company expenses sublicense payments as incurred unless they are related to revenues that have been deferred, in which case the expenses are deferred and recognized over the related revenue recognition period. The Company expenses maintenance payments as incurred.

Deferred collaboration expenses represent sub-license payments, paid to the Company's academic partners upon receipt of consideration from various commercial partners, and other consideration paid to our academic partners for modification to existing license agreements. These deferred expenses would not have been incurred without receipt of such payments or modifications from the Company's commercial partners and are being expensed in proportion to the related revenue being recognized. The Company believes that this accounting treatment appropriately matches expenses with the associated revenue.

Stock-Based Compensation

All share-based payments, including grants of stock option awards and restricted stock unit awards, are recognized in the Company's Consolidated Statements of Comprehensive Loss based on their fair values. The fair value of stock option awards is estimated using the Black-Scholes option pricing model. The fair value of restricted stock unit awards is based on the grant date closing price of the common stock. Stock-based compensation cost is recognized as expense on a straight-line basis over the requisite service period of the award. In addition, we have outstanding performance-based stock options for which no compensation expense is recognized until "performance" is deemed to have occurred.

Interest Expense and Deferred Financing Costs

Interest expense for the three months ended September 30, 2016 and 2015 was \$1,465 and \$1,241, respectively, and for the nine months ended September 30, 2016 and 2015 was \$4,356 and \$3,862, respectively, and primarily relates to the issuance of the Pharma Notes (defined in Note 4) and the Senior Credit Facility (defined in Note 5). Costs directly associated with the issuance of the Pharma Notes and the Senior Credit Facility have been capitalized and are netted against the non-recourse notes payable and Senior Credit Facility on the Consolidated Balance Sheets. These costs are being amortized to interest expense over the term of the Pharma Notes and the Senior Credit Facility using the effective interest rate method. Amortization of deferred financing costs included in interest expense was \$116 and \$110 for each of the three months ended September 30, 2016 and 2015, respectively. Amortization of deferred financing costs included in interest expense was \$335 and \$329 for each of the nine months ended September 30, 2016 and 2015, respectively.

Lease Financing Obligation

Based on the terms of the lease agreement for the new research facility in Birmingham, Alabama, the Company had construction period risks during the construction period and the Company was deemed the owner of the building (for accounting purposes only) during the construction period. Accordingly, the Company recorded an asset of \$1,589,

representing the Company's leased portion of the building and recorded a corresponding liability. Upon completion of leasehold improvement construction, the Company did not meet the sale-leaseback criteria for de-recognition of the building asset and liability. Therefore, the lease is accounted for as a financing obligation. The asset will be depreciated over the expected duration of the lease of 20.5 years, and rental payments will be treated as principal and interest payments on the lease financing obligation liability. The underlying accounting for this transaction has no impact on cash flows associated with the underlying lease or construction in process. Interest expense for the three and nine months ended September 30, 2016 includes \$86 and \$300, respectively, related to the lease financing obligation.

At September 30, 2016, the lease financing obligation balance was \$2,675 and was recorded as a long term liability on the consolidated balance sheets. The remaining future minimum payments under the lease financing obligation are \$4,839.

Currency Hedge Agreement

In connection with the issuance by Royalty Sub of the PhaRMA Notes, the Company entered into a Currency Hedge Agreement to hedge certain risks associated with changes in the value of the Japanese yen relative to the U.S. dollar. The Currency Hedge Agreement does not qualify for hedge accounting treatment; therefore, mark-to-market adjustments are recognized in the Company's Consolidated Statements of Comprehensive Loss. Cumulative mark-to-market adjustments for the nine months ended September 30, 2016 and 2015 resulted in losses of \$7,372 and \$793, respectively. Mark-to-market adjustments are determined by a third party pricing model that uses quoted prices in markets that are not actively traded and for which significant inputs are observable directly or indirectly, representing Level 2 in the fair value hierarchy as defined by U.S. GAAP. The Company is also required to post collateral in connection with the mark-to-market adjustments based on thresholds defined in the Currency Hedge Agreement. In addition, the Company realized currency exchange gains of \$811 and \$1,654 during the first nine months of 2016 and 2015, respectively, associated with the exercise of a U.S. dollar/Japanese yen currency option under the Currency Hedge Agreement. As of September 30, 2016, \$2,190 of hedge collateral was posted under the agreement. No hedge collateral was posted as of December 31, 2015.

Net Loss Per Share

Net loss per share is based upon the weighted average number of common shares outstanding during the period. Diluted loss per share is equivalent to basic net loss per share for all periods presented herein because common equivalent shares from unexercised stock options and common shares expected to be issued under the Company's employee stock purchase plan were anti-dilutive. The calculation of diluted earnings per share for the three months ended September 30, 2016 and 2015 does not include 1,291 and 3,821, respectively, of such potential common shares, as their impact would be anti-dilutive. The calculation of diluted earnings per share for the nine months ended September 30, 2016 and 2015 does not include 1,190 and 3,673, respectively, of such potential common shares, as their impact would be anti-dilutive.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires the Company to make estimates and assumptions that affect the amounts reported in the financial statements. Actual results could differ from those estimates.

Significant Customers and Other Risks

Significant Customers

Prior to the SUL Agreement, the Company relied primarily on three specialty distributors to purchase and supply the majority of RAPIVAB. These three pharmaceutical specialty distributors accounted for greater than 90% of all RAPIVAB product sales and accounted for predominantly all of the Company's outstanding receivables from product sales. The loss of one or more of these specialty distributors as a customer could negatively impact the commercialization of RAPIVAB. However, the Company will utilize these specialty distributors on a limited basis subsequent to the SUL collaboration as SUL, and other peramivir collaboration partners, will be responsible for commercial sales on a worldwide basis. In addition, in connection with the SUL collaboration, all peramivir sales (i.e., RAPIVAB, RAPIACTA, and PERAMIFLU) will be made by the Company's partners and the Company will be reliant on these partners to generate sales and remit cash to satisfy receivables.

The Company's primary source of revenue that has an underlying cash flow stream is the reimbursement of RAPIVAB and galidesivir (formerly BCX4430) development expenses earned under cost-plus-fixed-fee contracts with BARDA/HHS and NIAID/HHS. The Company relies on BARDA/HHS and NIAID/HHS to reimburse predominantly all of the development costs for its galidesivir program. Accordingly, reimbursement of these expenses represents a significant portion of the Company's collaborative and other research and development revenues. The completion (as with the June 30, 2014 BARDA/HHS peramivir development contract) or termination of the NIAID/HHS and BARDA/HHS galidesivir contracts could negatively impact the Company's future Consolidated Statements of Comprehensive Loss and Cash Flows. In addition, the Company also recognizes royalty revenue from the net sales of RAPIACTA by Shionogi; however, the underlying cash flow from these royalty payments, except for Japanese government stockpiling sales, goes directly to pay the interest, and then the principal, on the Company's non-recourse notes payable. Payment of the interest and the ultimate repayment of principal of these notes will be entirely funded by future royalty payments derived from net sales of RAPIACTA. Further, the Company's drug development activities are performed by a limited group of third party vendors. If any of these vendors were unable to perform their services, this could significantly impact the Company's ability to complete its drug development activities.

Risks from Third Party Manufacturing and Distribution Concentration

The Company relies on single source manufacturers for active pharmaceutical ingredient and finished drug product manufacturing of RAPIVAB, as well as for its other product candidates in development. Delays in the manufacture or distribution of any product could adversely impact the commercial revenue and future procurement stockpiling of RAPIVAB or the Company's product candidates in development.

Credit Risk

Cash equivalents and investments are financial instruments which potentially subject the Company to concentration of risk to the extent recorded on the Consolidated Balance Sheets. The Company deposits excess cash with major financial institutions in the United States. Balances may exceed the amount of insurance provided on such deposits. The Company believes it has established guidelines for investment of its excess cash relative to diversification and maturities that maintain safety and liquidity. To minimize the exposure due to adverse shifts in interest rates, the Company maintains a portfolio of investments with an average maturity of approximately 18 months or less. Other than product sale and collaborative partner receivables discussed above, the majority of the Company's receivables from collaborations are due from the U.S. Government, for which there is no assumed credit risk.

Recent Accounting Pronouncements

In August 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update No. 2016-15: *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments* ("ASU 2016-15"). The amendments in this update clarify how entities should classify certain cash receipts and cash payments on the Consolidated Statements of Cash Flows. The new guidance also clarifies how the predominance principle should be applied when cash receipts and cash payments have aspects of more than one class of cash flows. ASU 2016-15 will be effective for annual periods beginning after December 15, 2017, including interim periods within those annual reporting periods, but early adoption is permitted. The Company is currently evaluating the impact of this update on its consolidated financial statements.

In March 2016, the FASB issued Accounting Standards Update No. 2016-09: *Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting* (“ASU 2016-09”). The amendments in this update simplify several aspects of the accounting for employee share-based payment transactions, including the accounting for income taxes, forfeitures and statutory tax withholding requirements, as well as classification in the statement of cash flows. ASU 2016-09 will be effective for the Company in fiscal year 2017, but early adoption is permitted. The Company is currently evaluating the impact of this update on its consolidated financial statements.

In February 2016, the FASB issued Accounting Standards Update No. 2016-02: *Leases (Topic 842)* (“ASU 2016-02”). The amendments in this update require lessees, among other things, to recognize lease assets and lease liabilities on the balance sheet for those leases classified as operating leases under previous authoritative guidance. This update also introduces new disclosure requirements for leasing arrangements. ASU 2016-02 will be effective for the Company in fiscal year 2019, but early adoption is permitted. The Company is currently evaluating the impact of this update on its consolidated financial statements.

In January 2016, the FASB issued Accounting Standards Update No. 2016-01: *Financial Instruments - Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities* (“ASU 2016-01”). The amendments in this update address certain aspects of recognition, measurement, presentation and disclosure of financial instruments. In particular, the amendments in this update supersede, for public business entities, the requirement to disclose the methods and significant assumptions used in calculating the fair value of financial instruments required to be disclosed for financial instruments measured at amortized cost on the balance sheet. ASU 2016-01 will be effective for the Company in fiscal year 2018, but early adoption is permitted. The Company does not expect this standard to have a material impact on its consolidated financial statements.

In July 2015, the FASB issued Accounting Standards Update No. 2015-11: *Inventory (Topic 330): Simplifying the Measurement of Inventory* (“ASU 2015-11”), which changes the measurement principle for inventory from the lower of cost or market to the lower of cost and net realizable value. ASU 2015-11 defines net realizable value as the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The update does not apply to inventory that is measured using last-in, first-out or the retail inventory method. The update applies to all other inventory, which includes inventory that is measured using first-in, first-out or average cost methods. The amendments in ASU 2015-11 will be effective for the Company for fiscal years, and the interim periods within those years, beginning after December 15, 2016. The amendments must be applied prospectively and early adoption is permitted. The Company does not expect this standard to have a material impact on its consolidated financial statements.

In August 2014, the FASB issued Accounting Standards Update No. 2014-15: *Presentation of Financial Statements - Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern* (“ASU 2014-15”), which defines management’s responsibility to evaluate, at each annual and interim reporting period, whether there are conditions or events that raise substantial doubt about an entity’s ability to continue as a going concern within one year after the date the financial statements are issued and to provide related footnote disclosures in certain circumstances. In connection with each annual and interim period, management must assess if there is substantial doubt about the company’s ability to continue as a going concern within one year after the issuance

date. Disclosures are required if conditions give rise to substantial doubt. ASU 2014-15 is effective for all companies in the first annual period ending after December 15, 2016, and interim periods thereafter, with early adoption permitted. The Company is currently evaluating the impact this standard will have on its financial statements and disclosures.

In May 2014, the FASB issued Standards Update No. 2014-09: *Revenue from Contracts with Customers (Topic 606)* (“ASU 2014-09”), which provides a single, comprehensive revenue recognition model for all contracts with customers. The core principal of this ASU is that an entity should recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASU 2014-09 also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. In July 2015, the FASB finalized a one year delay in the effective date of this standard, which will now be effective January 1, 2018; however, early adoption is permitted any time after the original effective date, January 1, 2017. The Company is not electing early adoption. Companies can transition to the new standard under the full retrospective method or the modified retrospective method. The Company is currently evaluating the impact this standard will have on its consolidated financial statements.

Note 2 — Stock-Based Compensation

As of September 30, 2016, the Company had two stock-based employee compensation plans, the Stock Incentive Plan (“Incentive Plan”) and the Employee Stock Purchase Plan (“ESPP”). The Incentive Plan was amended and restated in April 2016 and approved by the Company’s stockholders in May 2016. The ESPP was amended and restated in March 2014 and approved by the Company’s stockholders in May 2014. Stock-based compensation expense of \$6,478 (\$6,331 of expense related to the Incentive Plan and \$147 of expense related to the ESPP) was recognized during the first nine months of 2016, while \$7,773 (\$7,553 of expense related to the Incentive Plan and \$220 of expense related to the ESPP) was recognized during the first nine months of 2015.

There was approximately \$16,591 of total unrecognized compensation cost related to non-vested stock option awards and restricted stock unit awards granted by the Company as of September 30, 2016. That cost is expected to be recognized as follows: \$1,889 during the remainder of 2016, \$6,958 in 2017, \$4,700 in 2018, \$2,633 in 2019 and \$411 in 2020. In addition, the Company has outstanding performance-based stock options for which no compensation expense is recognized until “performance” has occurred and the award vests. At the time of vesting, compensation expense will be recognized.

Stock Incentive Plan

The Company grants stock option awards and restricted stock unit awards to its employees, directors, and consultants under the Incentive Plan. Under the Incentive Plan, stock option awards are granted with an exercise price equal to the market price of the Company’s stock at the date of grant. Since March 1, 2011, stock option awards granted to employees generally vest 25% each year until fully vested after four years. In August 2013 and December 2014, the Company issued 1,032 and 1,250 performance-based stock options, respectively. These awards vest upon successful completion of specific development milestones. As of September 30, 2016, 75% of the August 2013 grants have vested based upon achievement of three milestones: (1) successful completion of the OPuS-1 clinical trial, for which vesting occurred in the second quarter of 2014, (2) FDA approval of RAPIVAB for which vesting occurred in the fourth quarter of 2014, and (3) initiation of a Phase 1 clinical trial to evaluate the safety, pharmacokinetics and pharmacodynamics of orally-administered BCX7353 in healthy volunteers, for which vesting occurred in the second quarter of 2015. Thus, as of September 30, 2016, 25% of the August 2013 performance-based grants and 100% of the December 2014 performance-based grants remain unvested and no compensation expense has been recognized for these portions of the previously issued performance-based grants. Stock option awards granted to non-employee directors of the Company generally vest monthly over one year. All stock option awards have contractual terms of 5 to 10 years. The vesting exercise provisions of all awards granted under the Incentive Plan are subject to acceleration in the event of certain stockholder-approved transactions, or upon the occurrence of a change in control as defined in the Incentive Plan.

Related activity under the Incentive Plan is as follows:

	Awards Available	Options Outstanding	Weighted Average Exercise Price
Balance December 31, 2015	16	10,671	\$ 7.50
Plan amendment	3,800	—	—
Restricted stock unit awards granted	(28)	—	—
Restricted stock unit awards cancelled	15	—	—
Stock option awards granted	(2,248)	2,248	3.20
Stock option awards exercised	—	(88)	2.23
Stock option awards cancelled	593	(593)	11.13
Balance September 30, 2016	2,148	12,238	\$ 6.57

For stock option awards granted under the Incentive Plan during the first nine months of 2016 and 2015, the fair value was estimated on the date of grant using a Black-Scholes option pricing model and the assumptions noted in the table below. The weighted average grant date fair value per share of the awards granted during the first nine months of 2016 and 2015 was \$2.17 and \$8.15, respectively. The fair value of the stock option awards is amortized to expense over the vesting periods using a straight-line expense attribution method. The following table summarizes the key assumptions used by the Company to value the stock option awards granted during the first nine months of 2016 and 2015. The expected life is based on the average of the assumption that all outstanding stock option awards will be exercised at full vesting and the assumption that all outstanding stock option awards will be exercised at the midpoint of the current date (if already vested) or at full vesting (if not yet vested) and the full contractual term. The expected volatility represents the historical volatility on the Company's publicly traded common stock. The Company has assumed no expected dividend yield, as dividends have never been paid to stock or option holders and will not be paid for the foreseeable future. The weighted average risk-free interest rate is the implied yield currently available on zero-coupon government issues with a remaining term equal to the expected term.

Weighted Average Assumptions for Stock Option Awards Granted to**Employees and Directors under the Incentive Plan**

	2016	2015
Expected Life in Years	5.5	5.5
Expected Volatility	82 %	83 %
Expected Dividend Yield	0.0 %	0.0 %
Risk-Free Interest Rate	1.4 %	1.5 %

Employee Stock Purchase Plan

The Company has reserved a total of 1,475 shares of common stock to be purchased under the ESPP, of which 422 shares remain available for purchase at September 30, 2016. Eligible employees may authorize up to 15% of their salary to purchase common stock at the lower of 85% of the beginning or 85% of the ending price during six-month purchase intervals. No more than 3 shares may be purchased by any one employee at the six-month purchase dates and no employee may purchase stock having a fair market value at the commencement date of \$25 or more in any one calendar year. The Company issued 75 shares during the first nine months of 2016 under the ESPP. Compensation expense for shares purchased under the ESPP related to the purchase discount and the “look-back” option were determined using a Black-Scholes option pricing model.

Note 3 — Collaborative and Other Research and Development Contracts

U.S. Department of Health and Human Services (“BARDA/HHS”). On March 31, 2015, the Company announced that BARDA/HHS had awarded the Company a contract for the continued development of galidesivir as a potential treatment for diseases caused by RNA pathogens, including filoviruses. This BARDA/HHS contract includes a base contract of \$16,265 to support galidesivir drug manufacturing, as well as \$22,855 in additional development options that can be exercised by the government, bringing the potential value of the contract to \$39,120. As of September 30, 2016, a total of \$20,574 has been awarded under exercised options within this contract.

National Institute of Allergy and Infectious Diseases (“NIAID/HHS”). In September 2013, NIAID/HHS contracted with the Company for the development of galidesivir as a treatment for Marburg virus disease. NIAID/HHS, part of the National Institutes of Health, made an initial award of \$5,000 to the Company. The goals of this contract, including amendments, are to file IND applications for intravenous (“i.v.”) and intramuscular (“i.m.”) galidesivir for the treatment of Marburg virus disease and other hemorrhagic fever virus diseases, to study galidesivir as a treatment for Ebola virus disease and to conduct an initial Phase 1 human clinical trial. As of September 30, 2016, the total NIAID/HHS contract amount to advance the program through the completion of the Phase I clinical program is \$39,477. As of September 30, 2016, all options have been exercised under this contract.

The contracts with BARDA/HHS and NIAID/HHS are cost-plus-fixed-fee contracts. That is, the Company is entitled to receive reimbursement for all costs incurred in accordance with the contract provisions that are related to the development of galidesivir plus a fixed fee, or profit. BARDA/HHS and NIAID/HHS will make periodic assessments of progress and the continuation of the contract is based on the Company's performance, the timeliness and quality of deliverables, and other factors. The government has rights under certain contract clauses to terminate these contracts. These contracts are terminable by the government at any time for breach or without cause.

Seqirus UK Limited ("SUL"). On June 16, 2015, the Company and Seqirus UK Limited ("SUL"), a limited company organized under the laws of the United Kingdom and a subsidiary of CSL Limited, a company organized under the laws of Australia, entered into a License Agreement (the "SUL Agreement") granting SUL and its affiliates worldwide rights to develop, manufacture and commercialize RAPIVAB (peramivir injection) for the treatment of influenza except for the rights to conduct such activities in Israel, Japan, Korea and Taiwan (the permitted geographies together constituting the "Territory"). RAPIVAB is an intravenous treatment for acute uncomplicated influenza and is currently licensed for use in the United States, Japan, Korea and Taiwan. RAPIVAB is the first and only intravenous influenza treatment in the world and was approved by the FDA in December 2014 for the treatment of acute uncomplicated influenza in patients 18 years and older who have been symptomatic for no more than two days. The Company retains all rights and associated economics to procure pandemic stockpiling orders for RAPIVAB from the U.S. Government, while SUL has the right to pursue government stockpiling outside the U.S.

Pursuant to the SUL Agreement, RAPIVAB will be commercialized by CSL's subsidiary, SUL, which specializes in influenza prevention through the supply of seasonal and pandemic vaccine to global markets. SUL will manufacture, commercialize and exercise decision-making authority with respect to the development and commercialization of RAPIVAB within the Territory and be responsible for all related costs, including sales and promotion.

In December 2013, the Company submitted an NDA for RAPIVAB to the FDA. Under the terms of the SUL Agreement, the Company is responsible for fulfilling all post-marketing approval commitments in connection with the FDA's approval of the NDA, and upon fulfillment will transfer ownership of and financial responsibility for the NDA to SUL. Pursuant to potential rights to sell RAPIVAB in Canada and the EU, the Company is also responsible for regulatory filings and interactions with the Health Canada and the European Medicines Agency ("EMA") until marketing approval for RAPIVAB is obtained and assigned to SUL. In January 2016, the Company submitted a New Drug Submission ("NDS") for RAPIVAB in Canada, seeking approval for treatment of acute uncomplicated influenza in adult patients. In accordance with the SUL Agreement, the Company and SUL formed a joint steering committee, composed of an equal number of representatives from each party, to oversee, review and coordinate the conduct and progress of the commercialization of RAPIVAB in the Territory and any additional development.

Under the terms of the SUL Agreement, the Company received an upfront payment of \$33,740, and may receive up to \$12,000 in additional milestone payments related to the successful achievement of regulatory milestones, including marketing approval (i) by the FDA for a pediatric indication, (ii) by the EMA for an adult indication in the EU and (iii) by Health Canada for an adult indication in Canada. The Company is also entitled under the SUL Agreement to receive tiered royalties at a percentage rate beginning in the mid-teens contingent upon meeting minimum thresholds of net sales, as well as a low-thirties percentage of the gross profit from government stockpiling purchases made outside the U.S. Specifically, the Company receives tiered royalties at a percentage rate in the mid-teens to low-forties on net sales in the U.S. during a Contract Year (defined as July 1 - June 30) and tiered royalties at a percentage rate in the mid-teens to mid-twenties on net sales in the Territory, other than in the U.S., during a Calendar Year, each subject to certain downward adjustments for circumstance or events impacting the overall market opportunity. SUL's royalty payment obligations commence on the date of the SUL Agreement and expire, on a country-by-country basis, upon the later of (i) the expiration of legal exclusivity in such country and (ii) ten years from the date of the SUL Agreement. The Company developed RAPIVAB under a license from UAB and will owe sublicense payments to them on any future milestone payments and/or royalties received by the Company from SUL.

Shionogi & Co., Ltd. ("Shionogi"). In February 2007, the Company entered into an exclusive license agreement with Shionogi to develop and commercialize peramivir in Japan for the treatment of seasonal and potentially life-threatening human influenza. Under the terms of the agreement, Shionogi obtained rights to injectable formulations of peramivir in Japan. The Company developed peramivir under a license from UAB and will owe sublicense payments to them on any future milestone payments and/or royalties received by the Company from Shionogi. In October 2008, the Company and Shionogi amended the license agreement to expand the territory covered by the agreement to include Taiwan. Shionogi has commercially launched peramivir under the commercial name RAPIACTA in Japan and Taiwan.

Green Cross Corporation (“Green Cross”). In June 2006, the Company entered into an agreement with Green Cross to develop and commercialize peramivir in Korea. Under the terms of the agreement, Green Cross will be responsible for all development, regulatory, and commercialization costs in Korea. The license also provides that the Company will share in profits resulting from the sale of peramivir in Korea, including the sale of peramivir to the Korean government for stockpiling purposes. Furthermore, Green Cross will pay the Company a premium over its cost to supply peramivir for development and any future marketing of peramivir products in Korea.

Mundipharma International Holdings Limited (“Mundipharma”). In February 2006, the Company entered into an exclusive, royalty bearing right and license agreement with Mundipharma for the development and commercialization of forodesine, a Purine Nucleoside Phosphorylase (“PNP”) inhibitor, for use in oncology. Under the terms of the license agreement, as amended, Mundipharma obtained rights to forodesine in markets across Europe, Asia, and Australasia in exchange for a \$10,000 up-front payment.

Albert Einstein College of Medicine of Yeshiva University and Industrial Research, Ltd. (“AECOM” and “IRL” respectively). In June 2000, the Company licensed a series of potent inhibitors of PNP from AECOM and IRL, (collectively, the “Licensors”). The lead product candidates from this collaboration are forodesine and ulodesine. The Company has obtained worldwide exclusive rights to develop and ultimately distribute these, or any other, product candidates that might arise from research on these inhibitors. The Company has the option to expand the Agreement to include other inventions in the field made by the investigators or employees of the Licensors. The Company agreed to use commercially reasonable efforts to develop these drugs. In addition, the Company has agreed to pay certain milestone payments for each licensed product (which range in the aggregate from \$1,400 to almost \$4,000 per indication) for future development of these inhibitors, single digit royalties on net sales of any resulting product made by the Company, and to share approximately one quarter of future payments received from other third-party partners, if any. In addition, the Company has agreed to pay annual license fees, which can range from \$150 to \$500, that are creditable against actual royalties and other payments due to the Licensors. This agreement may be terminated by the Company at any time by giving 60 days advance notice or in the event of material uncured breach by the Licensors.

In May 2010, the Company amended the licensee agreement through which the Company obtained worldwide exclusive rights to develop and ultimately distribute any product candidates that might arise from research on a series of PNP inhibitors, including forodesine and ulodesine. Under the terms of the amendment, the Licensors agreed to accept a reduction of one-half in the percentage of future payments received from third-party sub licensees of the licensed PNP inhibitors that must be paid to the Licensors. This reduction does not apply to (i) any milestone payments the Company may receive in the future under its license agreement dated February 1, 2006 with Mundipharma and (ii) royalties received from its sub licensees in connection with the sale of licensed products, for which the original payment rate will remain in effect. The rate of royalty payments to the Licensors based on net sales of any resulting product made by the Company remains unchanged.

On June 19, 2012, the Company further amended its agreements with AECOM/IRL whereby the parties clarified the definition of the field with respect to PNP inhibition and AECOM/IRL agreed to exclusive worldwide license of galidesivir to BioCryst for any antiviral use.

The University of Alabama at Birmingham (“UAB”). The Company currently has agreements with UAB for influenza neuraminidase and complement inhibitors. Under the terms of these agreements, UAB performed specific research for the Company in return for research payments and license fees. UAB has granted the Company certain rights to any discoveries in these areas resulting from research developed by UAB or jointly developed with the Company. The Company has agreed to pay single digit royalties on sales of any resulting product and to share in future payments received from other third-party partners. The Company has completed the research under the UAB agreements. These two agreements have initial 25-year terms, are automatically renewable for five-year terms throughout the life of the last patent and are terminable by the Company upon three months’ notice and by UAB under certain circumstances. Upon termination both parties shall cease using the other parties’ proprietary and confidential information and materials, the parties shall jointly own joint inventions and UAB shall resume full ownership of all UAB licensed products. There is currently no activity between the Company and UAB on these agreements, but when the Company licenses this technology, such as in the case of the Shionogi, Green Cross and SUL agreements, or commercializes products related to these programs, the Company will owe sublicense fees or royalties on amounts it receives.

Note 4 — Royalty Monetization

Overview

On March 9, 2011, the Company completed a \$30,000 financing transaction to monetize certain future royalty and milestone payments under the Shionogi Agreement, pursuant to which Shionogi licensed from the Company the rights to market RAPIACTA in Japan and Taiwan. The Company received net proceeds of \$22,691 from the transaction after transaction costs of \$4,309 and the establishment of a \$3,000 interest reserve account by Royalty Sub, available to help cover interest shortfalls in the future. All of the interest reserve account has been fully utilized with the September 2012 interest payment.

As part of the transaction, the Company entered into a purchase and sale agreement dated as of March 9, 2011 with Royalty Sub, whereby the Company transferred to Royalty Sub, among other things, (i) its rights to receive certain royalty and milestone payments from Shionogi arising under the Shionogi Agreement, and (ii) the right to receive payments under a Japanese yen/US dollar foreign currency hedge arrangement (as further described below, the “Currency Hedge Agreement”) put into place by the Company in connection with the transaction. Royalty payments will be paid by Shionogi in Japanese yen and milestone payments will be paid in U.S. dollars. The Company’s collaboration with Shionogi was not impacted as a result of this transaction.

Non-Recourse Notes Payable

On March 9, 2011, Royalty Sub completed a private placement to institutional investors of \$30,000 in aggregate principal amount of its PhaRMA Senior Secured 14.0% Notes due 2020 (the “PhaRMA Notes”). The PhaRMA Notes were issued by Royalty Sub under an Indenture, dated as of March 9, 2011 (the “Indenture”), by and between Royalty Sub and U.S. Bank National Association, as Trustee. Principal and interest on the PhaRMA Notes issued are payable from, and are secured by, the rights to royalty and milestone payments under the Shionogi Agreement transferred by the Company to Royalty Sub and payments, if any, made to Royalty Sub under the Currency Hedge Agreement. The PhaRMA Notes bear interest at 14% per annum, payable annually in arrears on September 1st of each year. The Company remains entitled to receive any royalties and milestone payments related to sales of peramivir by Shionogi following repayment of the PhaRMA Notes.

Royalty Sub’s obligations to pay principal and interest on the PhaRMA Notes are obligations solely of Royalty Sub and are without recourse to any other person, including the Company, except to the extent of the Company’s pledge of its equity interests in Royalty Sub in support of the PhaRMA Notes. The Company may, but is not obligated to, make capital contributions to a capital account that may be used to redeem, or on up to one occasion pay any interest shortfall on, the PhaRMA Notes.

On September 1, 2014, Royalty Sub was unable to pay the full amount of interest payable to avoid an event of default. Accordingly, the PhaRMA Notes and related accrued interest have been classified as current liabilities on the balance sheet. As a result of the event of default under the PhaRMA Notes, the holders of the PhaRMA Notes may pursue acceleration of the PhaRMA Notes, may foreclose on the collateral securing the PhaRMA Notes and the equity interest in Royalty Sub and exercise other remedies available to them under the Indenture in respect of the PhaRMA Notes. In such event, the Company may not realize the benefit of future royalty payments that might otherwise accrue to it following repayment of the PhaRMA Notes and it might otherwise be adversely affected. Due to the non-recourse nature of the PhaRMA Notes, in the event of any potential acceleration or foreclosure, the primary impact to the Company would be the loss of future royalty payments from Shionogi and legal costs associated with retiring the PhaRMA Notes. In addition, the Company may incur costs associated with liquidating the related Currency Hedge Agreement, which would no longer be required in the event of foreclosure, or if the PhaRMA Notes cease to be outstanding. As the PhaRMA Notes are the obligation of Royalty Sub and non-recourse to the Company, the event of default of the PhaRMA Notes is not expected to have a significant impact on the Company’s future results of operations or cash flows. As of September 30, 2016, the PhaRMA Notes remain in default.

As of September 30, 2016, the aggregate fair value of the PhaRMA Notes was estimated to be approximately 50% of its carrying value of \$30,000. The estimated fair value of the PhaRMA Notes is classified as Level 2 in the fair value hierarchy as defined in U.S. GAAP.

The PhaRMA Notes are redeemable at the option of Royalty Sub at any time at a redemption price equal to the outstanding principal balance of the PhaRMA Notes being redeemed plus accrued and unpaid interest through the redemption date on the PhaRMA Notes being redeemed.

Foreign Currency Hedge

In connection with the issuance by Royalty Sub of the PhaRMA Notes, the Company entered into a Currency Hedge Agreement to hedge certain risks associated with changes in the value of the Japanese yen relative to the U.S. dollar. Under the Currency Hedge Agreement, the Company has the right to purchase dollars and sell yen at a rate of 100 yen per dollar for which the Company may be required to pay a premium in each year from 2017 through 2020, provided the Currency Hedge Agreement remains in effect. A payment of \$1,950 will be required if, on May 18 of the relevant year, the U.S. dollar is worth 100 yen or less as determined in accordance with the Currency Hedge Agreement.

The Currency Hedge Agreement does not qualify for hedge accounting treatment; therefore, mark-to-market adjustments are recognized in the Company's Consolidated Statement of Comprehensive Loss. Cumulative mark-to-market adjustments for the nine months ended September 30, 2016 and 2015 resulted in losses of \$7,372 and \$793, respectively. The Company is also required to post collateral in connection with the mark-to-market adjustments based on defined thresholds. As of September 30, 2016, \$2,190 of hedge collateral was posted under the Currency Hedge Agreement. The Company will not be required to post collateral exceeding the maximum premium payments remaining payable under the Currency Hedge Agreement. As of September 30, 2016, the maximum amount of hedge collateral the Company may be required to post is \$7,800.

Note 5 — Senior Credit Facility

On September 23, 2016, the Company closed a \$23,000 Senior Credit Facility with an affiliate of MidCap Financial Services, LLC ("MidCap"), as administrative agent (the "Senior Credit Facility"). The Senior Credit Facility was fully funded at closing and bears a variable interest rate of LIBOR (which shall not be less than 0.5%) plus 8%. The Senior Credit Facility includes an interest-only payment period through fiscal 2017 and scheduled monthly principal and interest payments for the subsequent 40 months. The Company has the option to repay the Senior Credit Facility at any time prior to the scheduled principal repayment date subject to prepayment fees. Final payment of the Senior Credit Facility is subject to a final payment fee equal to 5% of the principal funded under the Senior Credit Facility.

As of September 30, 2016, the Company had borrowings of \$23,000 under the Senior Credit Facility bearing an interest rate of 8.5%. The carrying amount of the debt approximates its fair value based on prevailing interest rates as of the balance sheet date. Scheduled principal repayments of the Senior Credit Facility are as follows:

Principal Payments	
2017	\$—
2018	6,900
2019	6,900
2020	6,900
2021	2,300
Total	\$23,000

The debt agreement contains two provisions that if deemed probable would create the recognition of an embedded feature; however, at this time we do not believe either provision is probable.

Note 6 — Stockholders' Equity

On March 3, 2015, the Company filed a \$150,000 shelf registration statement on Form S-3 with the SEC. This shelf registration statement, as amended by a post-effective amendment filed on February 26, 2016 and declared effective on April 18, 2016, allows the Company to sell securities, including common stock, preferred stock, depository shares, stock purchase contracts, warrants and units, from time to time at prices and on terms to be determined at the time of sale.

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

This Quarterly Report on Form 10-Q contains statements of a forward-looking nature relating to future events or the future financial performance of BioCryst. Such statements are only predictions and the actual events or results may differ materially from the results discussed in the forward-looking statements. Factors that could cause or contribute to such differences include those discussed below and elsewhere in this report, as well as those discussed in other filings made by the Company with the Securities and Exchange Commission, including the Company’s Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. See “Information Regarding Forward-Looking Statements.”

Cautionary Statement

The discussion herein contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the “safe harbor” created in Section 21E. Forward looking statements regarding our financial condition and our results of operations that are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted within the United States (“U.S. GAAP”), as well as projections for the future. The preparation of these financial statements requires our management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. We evaluate our estimates on an ongoing basis. Our estimates are based on historical experience and on various other assumptions that are believed to be reasonable under the circumstances. The results of our estimates form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources.

We operate in a highly competitive environment that involves a number of risks, some of which are beyond our control. We are subject to risks common to biotechnology and biopharmaceutical companies, including risks inherent in our drug discovery, drug development and commercialization efforts, clinical trials, uncertainty of regulatory actions and marketing approvals, reliance on collaborative partners, enforcement of patent and proprietary rights, the need for future capital, competition associated with products, potential competition associated with our product candidates and retention of key employees. In order for any of our product candidates to be commercialized, it will be necessary for us, or our collaborative partners, to conduct clinical trials, demonstrate efficacy and safety of the product candidate to the satisfaction of regulatory authorities, obtain marketing approval, enter into manufacturing, distribution and marketing arrangements, and obtain market acceptance and adequate reimbursement from government and private insurers. We cannot provide assurance that we will generate significant revenues or achieve and sustain profitability in the future. In addition, we can provide no assurance that we will have sufficient funding to meet our future capital requirements. Statements contained in Management’s Discussion and Analysis of Financial Condition and Results of Operations and elsewhere in this report which are not historical facts are, or may constitute, forward-looking statements. Forward-looking statements involve known and unknown risks that could cause our actual results to differ materially from expected results. The most significant known risks are discussed in the section entitled “Risk Factors.” Although we believe the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. We caution you not to place undue reliance on any forward-looking statements.

Our revenues are difficult to predict and depend on numerous factors, including the prevalence and severity of influenza in regions for which peramivir has received regulatory approval, seasonality of influenza, ongoing discussions with government agencies regarding future peramivir and/or galidesivir development and stockpiling procurement, as well as entering into, or modifying, licensing agreements for our product candidates. Furthermore, revenues related to our collaborative development activities are dependent upon the progress toward and the achievement of developmental milestones by us or our collaborative partners.

Our operating expenses are also difficult to predict and depend on several factors, including research and development expenses (and whether these expenses are reimbursable under government contracts), drug manufacturing, and clinical research activities, the ongoing requirements of our development programs, and the availability of capital and direction from regulatory agencies, which are difficult to predict. Management may be able to control the timing and level of research and development and general and administrative expenses, but many of these expenditures will occur irrespective of our actions due to contractually committed activities and/or payments.

As a result of these factors, we believe that period to period comparisons are not necessarily meaningful and you should not rely on them as an indication of future performance. Due to all of the foregoing factors, it is possible that our operating results will be below the expectations of market analysts and investors. In such event, the prevailing market price of our common stock could be materially adversely affected.

Overview

We are a biotechnology company that designs, optimizes and develops novel small molecule drugs that block key enzymes involved in the pathogenesis of diseases. We focus on the treatment of rare diseases in which significant unmet medical needs exist and align with our capabilities and expertise. We integrate the disciplines of biology, crystallography, medicinal chemistry and computer modeling to discover and develop small molecule pharmaceuticals through the process known as structure-guided drug design.

Critical Accounting Policies and Estimates

The accompanying discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements and the related disclosures, which have been prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosure of contingent assets and liabilities. We evaluate our estimates, judgments and the policies underlying these estimates on a periodic basis, as situations change, and regularly discuss financial events, policies, and issues with members of our audit committee and our independent registered public accounting firm. We routinely evaluate our estimates and policies regarding revenue recognition, administration, inventory and manufacturing, taxes, stock-based compensation, research and development, consulting and other expenses and any associated liabilities.

Recent Corporate Highlights

RAPIVAB/RAPIACTA/PERAMIFLU (peramivir injection)

Peramivir (i.e., product sold under the RAPIVAB, RAPIACTA, and PERAMIFLU trade names) is approved for commercial sale in the United States, Japan, Taiwan and Korea. We receive royalty revenue from commercial and governmental sales of the product from our partners except for U.S. Government stockpiling sales for which we remain directly responsible. In the third quarter of 2016, our Japanese partner, Shionogi, sold a relatively large stockpiling order to the Japanese government in advance of the 2016/2017 influenza season for which we recorded \$3.5 million of net royalties. Proceeds from these stockpiling sales to the Japanese Government are available to us for general corporate use and are not dedicated to satisfying non-recourse obligations under the Pharma Notes.

BCX7353

In January 2015, we selected BCX7353 to advance into Phase 1 development as a once-daily, oral prophylactic hereditary angioedema (“HAE”) treatment. In October 2015, we successfully completed a Phase 1 clinical trial of BCX7353 in Western and Japanese healthy volunteers. In August 2016, we initiated a Phase 2 trial (“APeX-1”) to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and efficacy of BCX7353 for prophylaxis of angioedema attacks in patients with HAE in Canada and several European countries.

APeX-1 is a two-part, Phase 2, randomized, double-blind, placebo-controlled proof of concept and dose ranging trial studying BCX7353 as a preventative treatment to eliminate or reduce the frequency of angioedema attacks in HAE patients. Up to a total of approximately 50 eligible subjects with HAE will be enrolled in the trial.

In Part 1 of APeX-1, up to 36 subjects with HAE will be randomized in a 1:1 ratio to receive an oral dose of either 350 mg of BCX7353 once daily or placebo once daily for four weeks. An interim analysis will be conducted after the first 24 subjects have completed treatment through study day 28. If a robust treatment effect is observed at the interim analysis, Part 2 of the study will be initiated. In the event the treatment effect is not well characterized with 24 subjects, a total of up to approximately 36 subjects may be enrolled in part 1 under the existing protocol. The sample size in Part 1 was kept flexible to cover a range of response options. To characterize dose-response in part 2 of APeX-1, 14 additional subjects with HAE will be randomized to 250 mg of BCX7353 once daily (n=6), 125 mg of BCX7353 once daily (n=6) or placebo (n=2).

The primary efficacy endpoint of APeX-1 is the number of angioedema attacks; attack rate per week, counts of attacks, proportion of subjects with no attacks, and number of attack-free days. Secondary efficacy endpoints include severity and duration of angioedema attacks, and measures of health-related quality of life. Safety will be characterized through evaluation of adverse events and laboratory testing.

Galidesivir (formerly BCX4430)

On March 7, 2016, results from a preclinical study of our antiviral galidesivir in interferon-receptor-deficient mice infected with Zika virus were presented at a World Health Organization (WHO) conference in Geneva, Switzerland. The primary goal of the study was to assess the effect of galidesivir treatment on survival through Day 28 in interferon-receptor-deficient mice infected with the Zika virus. Galidesivir was administered by i.m. injection twice a day beginning four hours prior to virus challenge and continuing for eight days; two dose levels were tested. In the standard dose galidesivir group, 7 of 8 mice survived through Day 28. In the low dose galidesivir group (n=8), and in control groups administered vehicle placebo (n=8) or ribavirin at two dose levels (n=16); no animals survived to Day 28. Overall survival for the standard dose level of galidesivir was superior to both the placebo and the ribavirin treatment control groups ($p < 0.0001$). For both dose levels of galidesivir, median survival was superior to both control groups (>28 days for galidesivir standard dose and 23 days for low dose) compared to 14 to 17 days for controls.

Additional studies of galidesivir in the same mouse model were conducted at Utah State University. In one study, surviving mice that were previously treated with the standard dose of galidesivir after initial Zika virus challenge, were re-challenged with the Zika virus on Day 28, without additional galidesivir treatment. All the re-challenged mice survived through day 56 with no disease signs observed, indicating the development of effective immune responses. A further experiment using the same AG129 mouse model tested the delayed treatment with galidesivir after viral challenge. Groups of mice received galidesivir 150 mg/kg twice-daily by i.m. injection starting on days 1, 3, 5, or 7 post infection, or vehicle (control group). All galidesivir treated groups showed a statistically significant survival benefit compared to vehicle controls.

On October 29, 2016, galidesivir nonclinical results from a Zika virus infection model were presented in a late-breaker scientific session at IDWeek by Dr. James B. Whitney, PhD, Assistant Professor of Medicine, Harvard Medical School, and Principal Investigator in the Center for Virology and Vaccine Research at Beth Israel Deaconess Medical Center in Boston. Three groups of five healthy animals were inoculated with a Puerto Rico strain of Zika virus and administered either galidesivir by i.m. injection 200 mg/kg loading dose followed by 25 mg/kg BID for nine days, galidesivir single dose of 200 mg/kg, or vehicle control. Both galidesivir groups showed reduction in the proportion of animals viremic and in the amount of virus shed of into cerebrospinal fluid, saliva and urine. Galidesivir dosing in rhesus macaques was well-tolerated and offered significant protection against Zika virus infection. In a follow-on experiment, the same animals were rechallenged with a Thai strain of Zika virus, 72 days after initial inoculation. All animals demonstrated immune responses, and the initial treatments with galidesivir did not impair the generation of immunity.

Results of Operations (three months ended September 30, 2016 compared to the three months ended September 30, 2015)

For the three months ended September 30, 2016, total revenues were \$7.8 million as compared to \$11.0 million for the three months ended September 30, 2015. The decrease in revenue in the third quarter of 2016, as compared to 2015, resulted primarily from lower product revenue associated with the SUL agreement as well as lower collaborative revenue associated with galidesivir development in the third quarter of 2016, partially offset by higher royalty revenues from Shionogi & Co. during the third quarter of 2016. Revenues in the third quarter of 2016 included \$3.5 million of royalty revenue from Shionogi and Green Cross associated with sales of peramivir in the Japan, Korea and Taiwan, \$3.8 million of reimbursement of collaborative expenses from NIAID/HHS and BARDA/HHS related to the development of galidesivir, and \$0.4 million associated with collaborative revenue amortization from other corporate partnerships. Revenues in the third quarter of 2015 included \$5.7 million of RAPIVAB product revenue and \$0.2 million of collaborative revenue related to the SUL out-licensing transaction, \$0.1 million of royalty revenue from Shionogi and Green Cross associated with sales of peramivir in Japan and Korea, \$4.6 million of reimbursement of collaborative expenses from NIAID/HHS and BARDA/HHS related to the development of galidesivir and \$0.3 million associated with collaborative revenue amortization from other corporate partnerships.

Research and development (“R&D”) expenses decreased to \$14.1 million for the third quarter of 2016 from \$20.1 million in 2015. The decrease in 2016 R&D expenses, as compared to 2015, was primarily due to the discontinuation of avoralstat development in 2016.

General and administrative (“G&A”) expenses were \$2.8 million for the third quarter of 2016 and consistent with \$2.7 million in 2015. With the completion of the SUL transaction we do not anticipate incurring substantial commercial expenses to promote RAPIVAB in the future.

Interest expense, which is primarily related to the non-recourse notes issued in conjunction with the non-dilutive RAPIACTA royalty monetization transaction in March 2011, was \$1.5 million in the third quarter of 2016, compared to \$1.2 million in the third quarter of 2015.

A mark-to-market loss of \$0.9 million was also recognized in the third quarter of 2016 related to our foreign currency hedge, compared to a mark-to-market loss of \$0.5 million in the same quarter in the prior year, both resulting from changes in the U.S. dollar/Japanese yen exchange rate in the related time periods. In addition, we realized a currency exchange gain of \$0.1 million in the third quarter of 2015 related to the exercise of a U.S. dollar/Japanese yen currency option under our foreign currency hedge.

Results of Operations (nine months ended September 30, 2016 compared to the nine months ended September 30, 2015)

For the nine months ended September 30, 2016, total revenues were \$17.4 million as compared to \$43.7 million for the nine months ended September 30, 2015. The decrease in 2016 revenue was primarily due to recognizing \$21.7 million associated with an upfront payment from the SUL transaction in the first nine months of 2015, no longer recording product sales in 2016 associated with the SUL out-licensing transaction and a decrease in collaborative revenue associated with galidesivir development. Revenues in the first nine months of 2016 included \$6.0 million of royalty revenue from SUL, Shionogi and Green Cross associated with sales of peramivir in the United States, Japan, Korea and Taiwan, \$6.9 million of reimbursement of collaborative expenses from NIAID/HHS and BARDA/HHS related to the development of galidesivir, \$2.9 million of reimbursement of collaborative expenses from BARDA/HHS related to the development of RAPIVAB and \$1.5 million associated with collaborative revenue amortization from other corporate partnerships. Revenues in the first nine months of 2015 included \$5.7 million of RAPIVAB product revenue and \$21.7 million of collaborative revenue related to the SUL Agreement, \$1.8 million of royalty revenue from Shionogi and Green Cross associated with sales of peramivir in Japan and Korea, \$12.8 million of reimbursement of collaborative expenses from NIAID/HHS and BARDA/HHS related to the development of galidesivir and \$0.9 million associated with collaborative revenue amortization from other corporate partnerships. In addition, we recorded approximately \$0.6 million of RAPIVAB revenue under the “Sell-Through” revenue recognition methodology.

R&D expenses decreased to \$48.9 million for the first nine months of 2016 from \$53.7 million in 2015. The decrease in 2016 R&D expenses, as compared to 2015, reflects the discontinuation of avoralstat development, as well as reduced spending on our galidesivir program.

The following table summarizes our R&D expenses for the periods indicated (amounts are in thousands).

	Three Months		Nine Months	
	Ended		Ended	
	September 30,		September 30,	
	2016	2015	2016	2015
R&D expenses by program:				
Avoralstat	\$ 1,377	\$ 7,296	\$ 13,011	\$ 19,390
BCX7353	5,671	5,284	15,168	7,328
Galidesivir	3,462	3,394	7,213	9,746
2nd generation kallikrein inhibitors	141	1,024	1,139	9,087
RAPIVAB	1,017	647	4,679	2,685
Other research, preclinical and development costs	2,437	2,422	7,640	5,475
Total R&D expenses	\$ 14,105	\$ 20,067	\$ 48,850	\$ 53,711

G&A expenses decreased to \$8.7 million for the first nine months of 2016 as compared to \$10.3 million in 2015. The decrease of \$1.6 million was primarily due to lower unrestricted grants awarded to HAE patient advocacy groups, as well as a general reduction of administrative expenses in 2016.

Interest expense, which is primarily related to the non-recourse notes issued in conjunction with the non-dilutive RAPIACTA royalty monetization transaction in March 2011, was \$4.4 million in the first nine months of 2016, compared to \$3.9 million in the first nine months of 2015.

A mark-to-market loss of \$7.4 million was recognized in the first nine months of 2016 related to our foreign currency hedge, compared to a mark-to-market loss of \$0.8 million in the same period in the prior year, both resulting from changes in the U.S. dollar/Japanese yen exchange rate in the related time periods. In addition, we realized currency exchange gains of \$0.8 million and \$1.6 million, respectively, in the first nine months of 2016 and 2015 related to the exercise of a U.S. dollar/Japanese yen currency option under our foreign currency hedge.

Liquidity and Capital Resources

Cash expenditures have exceeded revenues since our inception and we expect our 2016 operating expenses to exceed our 2016 revenues. Our operations have principally been funded through public offerings and private placements of equity securities; cash from collaborative and other research and development agreements, including U.S. Government contracts for RAPIVAB and galidesivir; and to a lesser extent, the PhaRMA Notes financing and Senior Credit Facility with an affiliate of MidCap Financial Services, LLC (“MidCap”), as administrative agent (the “Senior Credit Facility”). To date, we have been awarded a BARDA/HHS RAPIVAB development contract totaling \$234.8 million, which expired on June 30, 2014, a NIAID/HHS galidesivir development contract totaling \$39.5 million, which is ongoing, and a BARDA/HHS galidesivir development contract totaling \$39.1 million, which is also ongoing. The total amount of NIAID/HHS and BARDA/HHS funding obligated under awarded options in the active contracts is \$39.5 million and \$20.6 million, respectively. We may issue securities through private placement transactions or registered public offerings pursuant to a registration statement filed with the SEC. In addition to the above, we have received funding from other sources, including other collaborative and other research and development agreements; government grants; equipment lease financing; facility leases; research grants; and interest income on our investments.

As of September 30, 2016, we had net working capital of \$13.1 million, an increase of approximately \$11.6 million from \$1.5 million at December 31, 2015. The increase in working capital was principally due to proceeds from the Senior Credit Facility offset by our normal operating expenses associated with the development of our product candidates. Our principal sources of liquidity at September 30, 2016 were approximately \$35.4 million in cash and cash equivalents and approximately \$31.8 million in investments considered available-for-sale. We anticipate our cash and investments will fund our operations into 2018.

We intend to contain costs and cash flow requirements by closely managing our third party costs and headcount, leasing scientific equipment and facilities, contracting with other parties to conduct certain research and development projects and using consultants. We expect to incur additional expenses, potentially resulting in significant losses, as we continue to pursue our research and development activities and begin to build a commercial infrastructure. We may incur additional expenses related to the filing, prosecution, maintenance, defense and enforcement of patent and other intellectual property claims and additional regulatory costs as our clinical programs advance through later stages of development. The objective of our investment policy is to ensure the safety and preservation of invested funds, as well as maintaining liquidity sufficient to meet cash flow requirements. We place our excess cash with high credit quality financial institutions, commercial companies, and government agencies in order to limit the amount of our credit exposure. We have not realized any significant losses on our investments.

We extended and executed additional lease obligations in 2015 for our Birmingham, Alabama operations, which increased the obligations by \$5.6 million and extended the new obligations out to 2027. These operating lease obligations encompass future rental obligations of our Birmingham operating facilities.

We plan to finance our needs principally from the following:

- lease or loan financing and future public or private equity financing;
- our existing capital resources and interest earned on that capital;
- payments under existing and executing new contracts with the U.S. Government; and
- payments under collaborative and licensing agreements with corporate partners.

As our programs continue to advance, our costs will increase. Our current and planned clinical trials, plus the related development, manufacturing, regulatory approval process requirements and additional personnel resources and testing required for the continuing development of our product candidates will consume significant capital resources and will increase our expenses. Our expenses, revenues and cash utilization rate could vary significantly depending on many factors, including our ability to raise additional capital, the development progress of our collaborative agreements for our product candidates, the amount and timing of funding we receive from existing U.S. Government contracts for galidesivir, the amount of funding or assistance, if any, we receive from new U.S. Government contracts or other new partnerships with third parties for the development and or commercialization of our product candidates, the progress and results of our current and proposed clinical trials for our most advanced product candidates, the progress made in the manufacturing of our lead product candidates and the progression of our other programs.

With the funds available at September 30, 2016, we believe these resources will be sufficient to fund our operations into 2018. Our future liquidity needs, and ability to address those needs, will largely be determined by the success of our product candidates and key development and regulatory events in the future. In order to continue our operations substantially beyond 2017, we will need to: (1) successfully secure or increase U.S. Government funding of our programs, including procurement contracts; (2) out-license rights to certain of our products or product candidates, pursuant to which we would receive cash milestones; (3) raise additional capital through equity or debt financings or from other sources; (4) obtain additional product candidate regulatory approvals, which would generate revenue and cash flow; (5) reduce spending on one or more research and development programs; and/or (6) restructure operations. We may issue securities through private placement transactions or registered public offerings pursuant to a registration statement filed with the SEC.

Our long-term capital requirements and the adequacy of our available funds will depend upon many factors, including:

- our ability to perform under our government contracts and receive reimbursement, and receive stockpiling procurement contracts;
- the magnitude of work under our government contracts;
- the progress and magnitude of our research, drug discovery and development programs;
- changes in existing collaborative relationships or government contracts;
- our ability to establish additional collaborative relationships with academic institutions, biotechnology or pharmaceutical companies and governmental agencies or other third parties;
- the extent to which our partners, including governmental agencies, will share in the costs associated with the development of our programs or run the development programs themselves;

- our ability to negotiate favorable development and marketing strategic alliances for certain product candidates or a decision to build or expand internal development and commercial capabilities;
- successful commercialization of marketed products by either us or a partner;
- the scope and results of preclinical studies and clinical trials to identify and develop product candidates;
- our ability to engage sites and enroll subjects in our clinical trials;
- the scope of manufacturing of our product candidates to support our preclinical research and clinical trials;
- increases in personnel and related costs to support the development and commercialization of our product candidates;
- the scope of manufacturing of our drug substance and product candidates required for future NDA filings;
- competitive and technological advances;
- the time and costs involved in obtaining regulatory approvals;
- post-approval commitments for RAPIVAB and other products that receive regulatory approval; and
- the costs involved in all aspects of intellectual property strategy and protection including the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims.

We expect that we will be required to raise additional capital to complete the development and commercialization of our current product candidates and we may seek to raise capital in the future. Additional funding, whether through additional sales of equity or debt securities, collaborative or other arrangements with corporate partners or from other sources, including governmental agencies in general and existing government contracts specifically, may not be available when needed or on terms acceptable to us. The issuance of preferred or common stock or convertible securities, with terms and prices significantly more favorable than those of the currently outstanding common stock, could have the effect of diluting or adversely affecting the holdings or rights of our existing stockholders. In addition, collaborative arrangements may require us to transfer certain material rights to such corporate partners. Insufficient funds may require us to delay, scale back or eliminate certain of our research and development programs. Our future working capital requirements, including the need for additional working capital, will be largely determined by the advancement of our portfolio of product candidates as well as rate of reimbursement by U.S. Government agencies of our galidesivir expenses and any future decisions regarding the future of the RAPIVAB and galidesivir programs, including those relating to stockpiling procurement. More specifically, our working capital requirements will be dependent on the number, magnitude, scope and timing of our development programs; regulatory approval of our product candidates; obtaining funding from collaborative partners; the cost, timing and outcome of regulatory reviews, regulatory investigations, and changes in regulatory requirements; the costs of obtaining patent protection for our product candidates; the timing and terms of business development activities; the rate of technological advances relevant to our operations; the efficiency of manufacturing processes developed on our behalf by third parties; and the level of required administrative support for our daily operations.

Financial Outlook for 2016

Based upon our development plans, expected operations and our awarded government contracts, we expect 2016 operating cash usage to be in the range of \$55 to \$75 million, and expect our total 2016 operating expenses to be in the range of \$68 to \$80 million. Our operating expense range excludes equity-based compensation expense due to the difficulty in accurately projecting this expense as it is significantly impacted by the volatility and price of the Company's stock, as well as vesting of the Company's outstanding performance-based stock options. Our operating cash forecast excludes any impact of our royalty monetization, hedge collateral posted or returned, and any other non-routine cash outflows or inflows. Our ability to remain within our operating expense and operating cash target ranges is subject to multiple factors, including unanticipated or additional general development and administrative costs and other factors described under the Risk Factors located elsewhere in this report.

Off-Balance Sheet Arrangements

As of September 30, 2016, we do not have any unconsolidated entities or off-balance sheet arrangements.

Critical Accounting Policies

We have established various accounting policies that govern the application of U.S. GAAP, which were utilized in the preparation of our consolidated financial statements. Certain accounting policies involve significant judgments and assumptions by management that have a material impact on the carrying value of certain assets and liabilities. Management considers such accounting policies to be critical accounting policies. The judgments and assumptions used by management are based on historical experience and other factors, which are believed to be reasonable under the circumstances. Because of the nature of the judgments and assumptions made by management, actual results could differ from these judgments and estimates, which could have a material impact on the carrying values of assets and liabilities and the results of operations.

While our significant accounting policies are more fully described in Note 1 to our consolidated financial statements included in our 2015 Annual Report on Form 10-K for the year ended December 31, 2015, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our reported financial results and affect the more significant judgments and estimates that we use in the preparation of our financial statements.

Inventory

Our inventories consist of RAPIVAB finished goods and work in process, which are valued at the lower of cost or market using the first-in, first-out (i.e., FIFO) method. Cost includes materials, labor, overhead, shipping and handling costs. Our inventories are subject to expiration dating. We regularly evaluate the carrying value of our inventories and provide valuation reserves for any estimated obsolete, short-dated or unmarketable inventories. In addition, we may experience spoilage of our raw materials and supplies. Our determination that a valuation reserve might be required, in addition to the quantification of such reserve, requires us to utilize significant judgment. In connection with the FDA approval of RAPIVAB in December 2014, we began capitalizing costs associated with the production of RAPIVAB commercial inventories.

Accrued Expenses

We enter into contractual agreements with third-party vendors who provide research and development, manufacturing, and other services in the ordinary course of business. Some of these contracts are subject to milestone-based invoicing and services are completed over an extended period of time. We record liabilities under these contractual commitments when an obligation has been incurred. This accrual process involves reviewing open contracts and purchase orders, communicating with our applicable personnel to identify services that have been performed and estimating the level of service performed and the associated cost when we have not yet been invoiced or otherwise notified of actual cost. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our accrued expenses as of each balance sheet date based on the facts and circumstances known to us. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Examples of estimated accrued expenses include:

- fees paid to Clinical Research Organizations (“CROs”) in connection with preclinical and toxicology studies and clinical trials;

- fees paid to investigative sites in connection with clinical trials;

- fees paid to contract manufacturers in connection with the production of our raw materials, drug substance and product candidates; and

- professional fees.

We base our expenses related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we will adjust the accrual accordingly. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of these costs, our actual expenses could differ from our estimates.

Revenue Recognition

We recognize revenues from collaborative and other research and development arrangements and product sales. Revenue is realized or realizable and earned when all of the following criteria are met: (i) persuasive evidence of an arrangement exists; (ii) delivery has occurred or services have been rendered; (iii) the seller's price to the buyer is fixed or determinable; and (iv) collectability is reasonably assured.

Collaborative and Other Research and Development Arrangements and Royalties

Revenue from license fees, royalty payments, event payments, and research and development fees are recognized as revenue when the earnings process is complete and we have no further continuing performance obligations or we have completed the performance obligations under the terms of the agreement. Fees received under licensing agreements that are related to future performance are deferred and recognized over an estimated period determined by management based on the terms of the agreement and the products licensed. In the event a license agreement contains multiple deliverables, we evaluate whether the deliverables are separate or combined units of accounting. Revisions to revenue or profit estimates as a result of changes in the estimated revenue period are recognized prospectively.

Under certain of our license agreements, we receive royalty payments based upon our licensees' net sales of covered products. We recognize royalty revenues when we can reliably estimate such amounts and collectability is reasonably assured. Royalty revenue paid by Shionogi on their product sales is subject to returns.

For arrangements that involve the delivery of more than one element, each product, service and/or right to use assets is evaluated to determine whether it qualifies as a separate unit of accounting. This determination is based on whether the deliverable has "stand-alone value" to the customer. The consideration that is fixed or determinable is then allocated to each separate unit of accounting based on the relative selling price of each deliverable. The estimated selling price of each deliverable is determined using the following hierarchy of values: (i) vendor-specific objective evidence of fair value, (ii) third-party evidence of selling price ("TPE") and (iii) best estimate of selling price ("BESP"). The BESP reflects our best estimate of what the selling price would be if the deliverable was regularly sold by us on a stand-alone basis. In most cases we expect to use TPE or BESP for allocating consideration to each deliverable. The consideration allocated to each unit of accounting is recognized as the related goods or services are delivered, limited to the consideration that is not contingent upon future deliverables. Analyzing the arrangement to identify deliverables requires the use of judgment, and each deliverable may be an obligation to deliver services, a right or license to use an asset, or another performance obligation.

In June 2015, we entered into a License Agreement (the "SUL Agreement") granting SUL and its affiliates worldwide rights, excluding Israel, Japan, Korea and Taiwan, to develop, manufacture and commercialize RAPIVAB. The SUL Agreement provides for various types of payments, including a non-refundable upfront fee, milestone payments, and future royalties. Analysis of the SUL Agreement identified three deliverables: (i) license rights, (ii) inventory and (iii) regulatory support to obtain Canadian and EU marketing approvals. We received an upfront payment of \$33.7 million from SUL of which \$7.0 million was determined to be contingent upon EU marketing approval and will be deferred until that time. Approximately \$21.7 million of the upfront payment was allocated to the license rights and recognized as revenue in the second quarter. Approximately \$3.7 million of the upfront payment was allocated to the sale of inventory and was recognized in the third quarter when the inventory transfer was completed. Approximately \$1.2 million of the revenue from the SUL Agreement will be recognized ratably over the expected period of involvement in these regulatory support activities.

Milestone payments are recognized as licensing revenue upon the achievement of specified milestones if (i) the milestone is substantive in nature and the achievement of the milestone was not reasonably assured at the inception of the SUL Agreement; and (ii) the fees are non-refundable. Any milestone payments received prior to satisfying these revenue recognition criteria are recorded as deferred revenue.

Under the terms of the SUL Agreement, we may receive up to \$12.0 million in additional payments related to the successful achievement of regulatory milestones, including marketing approval (i) by the FDA for a pediatric indication, (ii) by the EMA for an adult indication in the EU and (iii) by Health Canada for an adult indication in Canada. We evaluated each event based payment under the provisions of ASU 2010-17, *Milestone Method of Revenue Recognition*, and determined that each event based payment met the criteria to be considered substantive and represents a milestone under the milestone method of accounting. No event based payments were achieved during the periods presented.

Reimbursements received for direct out-of-pocket expenses related to research and development costs are recorded as revenue in the income statement rather than as a reduction in expenses. Under our contracts with BARDA/HHS and NIAID/HHS, revenue is recognized as reimbursable direct and indirect costs are incurred.

Product Sales

We recognize revenue for sales of RAPIVAB when title and substantially all the risks and rewards of ownership have transferred to the customer, which generally occurs on the date of shipment from our specialty distributors, utilizing the Sell-Through revenue recognition methodology. Product sales are recognized when there is persuasive evidence that an arrangement exists, title has passed, the price was fixed and determinable, and collectability is reasonably assured. Product sales are recognized net of estimated allowances, discounts, sales returns, chargebacks and rebates. In the United States, prior to completion of the SUL transaction, we sold RAPIVAB to specialty distributors, who, in turn, sell to physician offices, hospitals and federal, state and commercial health care organizations. With the completion of the SUL worldwide license of RAPIVAB, SUL will be responsible for sales of RAPIVAB, other than U.S. Government stockpiling sales. With the completion of the SUL collaboration, all peramivir sales (i.e., RAPIVAB, RAPIACTA, and PERAMIFLU) will be made by the Company's partners, except for U.S. Government stockpiling sales, and the Company will be reliant on these partners to generate sales and provide for sales discounts and rebates.

Sales deductions consist of statutory rebates to state Medicaid, Medicare and other government agencies and sales discounts (including trade discounts and distribution service fees). These deductions are recorded as reductions to revenue from RAPIVAB in the same period as the related sales with estimates of future utilization derived from historical experience adjusted to reflect known changes in the factors that impact such reserves.

We utilize data from external sources to help estimate gross-to-net sales adjustments as they relate to the recognition of revenue for RAPIVAB sold. External sourced data includes, but is not limited to, information obtained from specialty distributors with respect to their inventory levels and sell-through to customers, and information from third-party suppliers of market research data to the pharmaceutical industry.

We have categorized and described more fully the following significant sales deductions, all of which involve estimates and judgments, which we consider to be critical accounting estimates, and requires us to use information from external sources.

Rebates and Chargebacks

Statutory rebates to state Medicaid agencies and Medicare are based on statutory discounts to RAPIVAB's selling price. As it can take up to nine months or more for information to be received on actual usage of RAPIVAB in Medicaid and other governmental programs, we maintain reserves for amounts payable under these programs relating to RAPIVAB sales.

Chargebacks claimed by specialty distributors are based on the differentials between product acquisition prices paid by the specialty distributors and lower government contract pricing paid by eligible customers covered under federally qualified programs.

The amount of the reserve for rebates and chargebacks is based on multiple qualitative and quantitative factors, including the historical and projected utilization levels, historical payment experience, changes in statutory laws and interpretations as well as contractual terms, product pricing (both normal selling prices and statutory or negotiated prices), changes in prescription demand patterns and utilization of our product through public benefit plans, and the levels of RAPIVAB inventory in the distribution channel. We acquire prescription utilization data from third-party suppliers of market research data to the pharmaceutical industry. We update our estimates and assumptions each period and record any necessary adjustments to reserves. Settlements of rebates and chargebacks typically occur within nine months from point of sale. To the extent actual rebates and chargebacks differ from our estimates, additional reserves may be required or reserves may need to be reversed, either of which would impact current period product revenue.

Discounts and Sales Incentives

Discounts and other sales incentives primarily consist of Inventory Management Agreement (“IMA”) fees. Per contractual agreements with our specialty distributors, we provide an IMA fee based on a percentage of their purchases of RAPIVAB. The IMA fee rates are set forth in our individual contracts. We track sales to our specialty distributors each period and accrue a liability relating to the unpaid portion of these fees by applying contractual rates to such sales.

Product Returns

We do not record a product return allowance as we do not offer the ability to return goods once a bona fide shipment has been accepted by a specialty distributor.

Research and Development Expenses

Our research and development costs are charged to expense when incurred. Advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts are recognized as expense when the related goods are delivered or the related services are performed. Research and development expenses include, among other items, personnel costs, including salaries and benefits, manufacturing costs, clinical, regulatory, and toxicology services performed by CROs, materials and supplies, and overhead allocations consisting of various administrative and facilities related costs. Most of our manufacturing and clinical and preclinical studies are performed by third-party CROs. Costs for studies performed by CROs are accrued by us over the service periods specified in the contracts and estimates are adjusted, if required, based upon our on-going review of the level of services actually performed.

Additionally, we have license agreements with third parties, such as AECOM, IRL, and UAB, which require fees related to sublicense agreements or maintenance fees. We expense sublicense payments as incurred unless they are related to revenues that have been deferred, in which case the expenses are deferred and recognized over the related revenue recognition period. We expense maintenance payments as incurred.

Deferred collaboration expenses represent sub-license payments paid to our academic partners upon receipt of consideration from various commercial partners, and other consideration to our academic partners for modification to existing license agreements. These deferred expenses would not have been incurred without receipt of such payments or modifications from our commercial partners and are being expensed in proportion to the related revenue being recognized. We believe that this accounting treatment appropriately matches expenses with the associated revenue.

We group our R&D expenses into two major categories: direct external expenses and indirect expenses. Direct expenses consist of compensation for R&D personnel and costs of outside parties to conduct laboratory studies, develop manufacturing processes and manufacture the product candidate, conduct and manage clinical trials, as well as other costs related to our clinical and preclinical studies. These costs are accumulated and tracked by active program. Indirect expenses consist of lab supplies and services, facility expenses, depreciation of development equipment and other overhead of our research and development efforts. These costs apply to work on non-active product candidates and our discovery research efforts.

Stock-Based Compensation

All share-based payments, including grants of stock option awards and restricted stock unit awards, are recognized in our Consolidated Statements of Comprehensive Loss based on their fair values. Stock-based compensation cost is estimated at the grant date based on the fair value of the award and is recognized as expense on a straight-line basis over the requisite service period of the award. Determining the appropriate fair value model and the related assumptions for the model requires judgment, including estimating the life of an award, the stock price volatility, and the expected term. We utilize the Black-Scholes option-pricing model to value our awards and recognize compensation expense on a straight-line basis over the vesting periods. The estimation of share-based payment awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from our current estimates, such amounts will be recorded as a cumulative adjustment in the period estimates are revised. In addition, we have outstanding performance-based stock options for which no compensation expense is recognized until “performance” has occurred. Significant management judgment is also required in determining estimates of future stock price volatility and forfeitures to be used in the valuation of the options. Actual results, and future changes in estimates, may differ substantially from our current estimates.

Currency Hedge Agreement

In connection with our issuance of the PhaRMA Notes, we entered into a foreign Currency Hedge Agreement to hedge certain risks associated with changes in the value of the Japanese yen relative to the U.S. dollar. Under the Currency Hedge Agreement, we have the right to purchase dollars and sell yen at a rate of 100 yen per dollar for which we may be required to pay a premium in each year from 2017 through 2020, provided the Currency Hedge Agreement remains in effect. A payment of \$2.0 million will be required if, on May 18 of the relevant year, the U.S. dollar is worth 100 yen or less as determined in accordance with the Currency Hedge Agreement. In conjunction with establishing the Currency Hedge Agreement, we will be required to post collateral to the counterparty, which may cause us to experience additional quarterly volatility in our financial results. We will not be required at any time to post collateral exceeding the maximum premium payments remaining payable under the Currency Hedge Agreement. In establishing the hedge, we provided initial funds of approximately \$2.0 million to support our potential hedge obligations. As of September 30, 2016, the maximum amount of hedge collateral we may be required to post is \$7.8 million.

The Currency Hedge Agreement does not qualify for hedge accounting treatment and therefore mark to market adjustments will be recognized in our Consolidated Statements of Comprehensive Loss. Mark to market adjustments are determined by quoted prices in markets that are not actively traded and for which significant inputs are observable directly or indirectly, representing the Level 2 in the fair value hierarchy as defined by generally accepted accounting principles (“U.S. GAAP”). The Company is also required to post collateral in connection with the mark to market adjustments based on defined thresholds. As of September 30, 2016, \$2.2 million of collateral was posted under the agreement.

Tax

We account for uncertain tax positions in accordance with U.S. GAAP. Significant management judgment is required in determining our provision for income taxes, deferred tax assets and liabilities and any valuation allowance recorded against net deferred tax assets. We have recorded a valuation allowance against all potential tax assets, due to uncertainties in our ability to utilize deferred tax assets, primarily consisting of certain net operating losses carried forward, before they expire. The valuation allowance is based on estimates of taxable income in each of the jurisdictions in which we operate and the period over which our deferred tax assets will be recoverable.

Information Regarding Forward-Looking Statements

This filing contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the “safe harbor” created in Section 21E. All statements other than statements of historical facts contained in this filing are forward-looking statements. These forward-looking statements can generally be identified by the use of words such as “may,” “will,” “intends,” “plans,” “believes,” “anticipates,” “expects,” “estimates,” “predicts,” “potential,” the negative of these words or similar expressions. Statements that describe our future plans, strategies, intentions, expectations, objectives, goals or prospects are also forward-looking statements. Discussions containing these forward-looking statements are principally contained in “Business,” “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” as well as any amendments we make to those sections in filings with the SEC. These forward-looking statements include, but are not limited to, statements about:

- the preclinical development, clinical development, commercialization, or post-marketing studies of our product candidates and products, including our HAE program, RAPIVAB, galidesivir, and early stage discovery programs;
- the potential funding from our contracts with NIAID/HHS and BARDA/HHS for the development of galidesivir;
- the potential for government stockpiling orders of RAPIVAB, additional regulatory approvals of RAPIVAB or milestones royalties or profit from sales of peramivir by us or our partners;
- the potential use of RAPIVAB as a treatment for H1N1, H5N1, and H7N9 or other strains of influenza;
- the implementation of our business model, strategic plans for our business, products, product candidates and technology;
- our ability to establish and maintain collaborations or out-license rights to our drug candidates;
- plans, programs, progress and potential success of our collaborations, including SUL for RAPIVAB, Mundipharma for forodesine and Shionogi and Green Cross for peramivir in their territories;
- Royalty Sub’s ability to service its payment obligations in respect of the PhaRMA Notes, and our ability to benefit from our equity interest in Royalty Sub;
- the foreign currency hedge agreement entered into by us in connection with the issuance by Royalty Sub of the PhaRMA Notes;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- our ability to operate our business without infringing the intellectual property rights of others;
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estimates of our expenses, revenues, capital requirements, annual cash utilization, and our needs for additional financing;

- the timing or likelihood of regulatory filings or regulatory agreements, deferrals, and approvals;
- our ability to raise additional capital to fund our operations or repay our recourse debt obligations;
- our ability to comply with the covenants as set forth in the agreements governing our debt obligations;
- our financial performance; and
- competitive companies, technologies and our industry.

These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under “Risk Factors.” Any forward-looking statement reflects our current views with respect to future events and is subject to these and other risks, uncertainties and assumptions relating to our operations, results of operations, industry and future growth. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

We are subject to interest rate risk on our investment portfolio and borrowings under our fixed-interest rate PhaRMA Notes and our variable-interest rate Senior Credit Facility. The interest rate applicable to our borrowings under the Senior Credit Facility is based on LIBOR. Increases in interest rates could therefore increase the associated interest payments that the Company is required to make on this debt. As of September 30, 2016, the Company had borrowings of \$23 million under the Senior Credit Facility bearing an interest rate of 8.5%.

We invest in marketable securities in accordance with our investment policy. The primary objectives of our investment policy are to preserve capital, maintain proper liquidity to meet operating needs and maximize yields. Our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure to any single issue, issuer or type of investment. We place our excess cash with high credit quality financial institutions, commercial companies, and government agencies in order to limit the amount of credit exposure. Some of the securities we invest in may have market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate.

Our investment exposure to market risk for changes in interest rates relates to the increase or decrease in the amount of interest income we can earn on our portfolio, changes in the market value due to changes in interest rates and other market factors as well as the increase or decrease in any realized gains and losses. Our investment portfolio includes only marketable securities and instruments with active secondary or resale markets to help ensure portfolio liquidity. A hypothetical 100 basis point drop in interest rates along the entire interest rate yield curve would not significantly affect the fair value of our interest sensitive financial instruments, including our borrowings. We generally have the ability to hold our fixed-income investments to maturity and therefore do not expect that our operating results, financial position or cash flows will be materially impacted due to a sudden change in interest rates. However, our future investment income may fall short of expectations due to changes in interest rates, or we may suffer losses in principal if forced to sell securities which have declined in market value due to changes in interest rates or other factors, such as changes in credit risk related to the securities' issuers. To minimize this risk, we schedule our investments to have maturities that coincide with our expected cash flow needs, thus avoiding the need to redeem an investment prior to its maturity date. Accordingly, we do not believe that we have material exposure to interest rate risk arising from our investments. Generally, our investments are not collateralized. We have not realized any significant losses from our investments.

We do not use interest rate derivative instruments to manage exposure to interest rate changes. We ensure the safety and preservation of invested principal funds by limiting default risk, market risk and reinvestment risk. We reduce default risk by investing in investment grade securities.

Foreign Currency Risk

The majority of our transactions occur in U.S. dollars and we do not have operating subsidiaries or investments in foreign countries. Therefore, we are not subject to significant foreign currency exchange risk in our normal operations.

In connection with the issuance by Royalty Sub of the PhaRMA Notes, we entered into a Currency Hedge Agreement to hedge certain risks associated with changes in the value of the Japanese yen relative to the U.S. dollar. Under the Currency Hedge Agreement, we are required to post collateral based on our potential obligations under the Currency Hedge Agreement as determined by periodic mark-to-market adjustments. Provided the Currency Hedge Agreement remains in effect, we may be required to pay an annual premium in the amount of \$2.0 million from May 2017 through May 2020. Such payment will be required if, in May of the relevant year, the spot rate of exchange for

Japanese yen-U.S. dollars (determined in accordance with the Currency Hedge Agreement) is such that the U.S. dollar is worth 100 yen or less.

Item 4. Controls and Procedures

We maintain a set of disclosure controls and procedures that are designed to ensure that information relating to BioCryst Pharmaceuticals, Inc. required to be disclosed in our periodic filings under the Exchange Act is recorded, processed, summarized and reported in a timely manner under the Exchange Act. We carried out an evaluation, under the supervision and with the participation of management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that, as of September 30, 2016, the Company's disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company in the reports filed or submitted by it under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and include controls and procedures designed to ensure that information required to be disclosed by the Company in such reports is accumulated and communicated to the Company's management, including the Chief Executive Officer and Chief Financial Officer of the Company, as appropriate to allow timely decisions regarding required disclosure.

There have been no changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2016 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1A. RISK FACTORS

An investment in our stock involves risks. You should carefully read this entire report and consider the following uncertainties and risks, which may adversely affect our business, financial condition or results of operations, along with all of the other information included in our other filings with the Securities and Exchange Commission, before deciding to buy our common stock.

Risks Relating to Our Business

We have incurred losses since our inception, expect to continue to incur such losses, and may never be profitable.

Since our inception, we have not achieved sustained profitability. We expect to incur additional losses for the foreseeable future, and our losses could increase as our research and development efforts progress. We expect that such losses will fluctuate from quarter to quarter and losses and fluctuations may be substantial.

To become profitable, we, or our collaborative partners, must successfully manufacture and develop product candidates, receive regulatory approval, and successfully commercialize and/or enter into profitable agreements with other parties. It could be several years, if ever, before we receive significant revenue from any current or future license agreements or revenues directly from product sales.

Because of the numerous risks and uncertainties associated with developing our product candidates and their potential for commercialization, we are unable to predict the extent of any future losses. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we are unable to achieve and sustain profitability, the market value of our common stock will likely decline.

Our success depends upon our ability to advance our products through the various stages of development, especially through the clinical trial process.

To receive the regulatory approvals necessary for the sale of our product candidates, we or our partners must demonstrate through preclinical studies and clinical trials that each product candidate is safe and effective. The development process and related regulatory process are complex and uncertain. Because of the cost and duration of clinical trials, we may decide to discontinue development of product candidates that are unlikely to show good results in the clinical trials, unlikely to help advance a product to the point of a meaningful collaboration, or unlikely to have reasonable commercial potential. We may suffer significant setbacks in pivotal pre-clinical studies and clinical trials (e.g. galidesivir, BCX7353, other kallikrein inhibitors and our other rare disease product candidates), even after earlier clinical trials show promising results. The development of our product candidates, including our clinical trials, may not be adequately designed or executed, which could affect the potential outcome and analysis of study results. Any of our product candidates may produce undesirable side effects in humans. The pre-clinical and clinical data from our product candidates could cause us or regulatory authorities to interrupt, delay, modify or halt preclinical or clinical trials of a product candidate. Undesirable or inconclusive data or side effects in humans could also result in the FDA or foreign regulatory authorities refusing to approve the product candidate for any targeted indications. In addition, the FDA or other regulatory agencies may determine that study data from our product candidates necessitates additional studies or study designs which differ from our planned development strategy, and regulatory agencies may also require patient monitoring and testing or may implement restrictions or other conditions on our development activities, any of which could materially impact the cost and timing of our planned development strategy. We, our partners, the FDA or foreign regulatory authorities may suspend or terminate clinical trials at any time if we or they believe the trial participants face unacceptable health risks. Clinical trials may fail to demonstrate that our product candidates are safe or effective and have acceptable commercial viability. Regulatory authorities may interrupt, delay or halt clinical trials for a product candidate for any number of reasons.

Our ability to successfully complete clinical trials is dependent upon many factors, including but not limited to:

- our ability to find suitable clinical sites and investigators to enroll patients;
- the ability to maintain contact with patients to provide complete data after treatment;
- our product candidates may not prove to be either safe or effective;
- clinical protocols or study procedures may not be adequately designed or followed by the investigators;
- formulation improvements may not work as expected, which could negatively impact commercial demand for our product candidates;
- manufacturing or quality control problems could affect the supply of product candidates for our trials; and
- delays or changes in our planned development strategy, the regulations or guidelines, or other unexpected conditions or requirements of government agencies.

Clinical trials are lengthy and expensive. We or our partners incur substantial expense for, and devote significant time to, preclinical testing and clinical trials, yet we cannot be certain that the tests and trials will ever result in the commercial sale of a product. For example, clinical trials require adequate supplies of drug and sufficient patient enrollment. Lack of adequate drug supply or delays in patient enrollment can result in increased costs and longer development times. Even if we or our partners successfully complete clinical trials for our product candidates, we or our partners might not file the required regulatory submissions in a timely manner and may not receive regulatory approval for the product candidates.

We focus on rare diseases, which may create additional risks and challenges.

Because we focus on developing drugs as treatments for rare diseases, we may seek orphan drug, breakthrough therapy or fast track designations for our product candidates in the United States or the equivalent designations elsewhere in the world. Often, regulatory agencies have broad discretion in determining whether or not to grant such designations. We cannot guarantee that we will be able to receive orphan drug status from the FDA or equivalent regulatory designations elsewhere. We also cannot guarantee that we will obtain breakthrough therapy or fast track designation, which may provide certain potential benefits such as more frequent meetings with the FDA to discuss the development plan, intensive guidance on an efficient drug development program, and potential eligibility for rolling review or priority review. Even if we are successful in obtaining any such designation by the FDA or other regulatory agency for our product candidates, such designations may not lead to faster development or regulatory review or approval, and it does not increase the likelihood that our product candidates will receive marketing approval. We may not be able to obtain or maintain such designations for our product candidates, and our competitors may obtain these designations for their product candidates, which could impact our ability to develop and commercialize our product candidates or compete with such competitors, which may adversely impact our business, financial condition or results of operations.

Although we have received Sakigake designation for BCX7353 in Japan, we may not experience a faster development, review or approval process compared to the conventional process.

Our clinical trials may not adequately show that our product candidates are safe or effective.

Progression of our product candidates through the clinical development process is dependent upon our trials indicating our product candidates have adequate safety and efficacy in the patients being treated by achieving pre-determined safety and efficacy endpoints according to the clinical trial protocols. Failure to achieve any of these endpoints in any of our programs, including BCX7353, and our other rare disease product candidates, could result in delays in our trials or require the performance of additional unplanned trials. This could result in delays in the development of our product candidates and could result in significant unexpected costs or the termination of programs.

If our development collaborations with third parties, such as our development partners and contract research organizations, fail, the development of our product candidates will be delayed or stopped.

We rely heavily upon third parties for many important stages of our product candidate development, including but not limited to:

- discovery of compounds that cause or enable biological reactions necessary for the progression of the disease or disorder, called enzyme targets;
 - licensing or designing of enzyme inhibitors for development as product candidates;
 - execution of certain preclinical studies and late-stage development for our compounds and product candidates;
 - management of our clinical trials, including medical monitoring and data management;
 - execution of additional toxicology studies that may be required to obtain approval for our product candidates;
 - formulation improvement strategies and methods; and
- manufacturing the starting materials and drug substance required to formulate our products and the product candidates to be used in our clinical trials, toxicology studies and any potential commercial product.

Our failure to engage in successful collaborations at any one of these stages would greatly impact our business. If we do not license enzyme targets or inhibitors from academic institutions or from other biotechnology companies on acceptable terms, our drug development efforts would suffer. Similarly, if the contract research organizations that conduct our initial or late-stage clinical trials, conduct our toxicology studies, manufacture our starting materials, drug substance and product candidates or manage our regulatory function breached their obligations to us or perform their services inconsistent with industry standards and not in accordance with the required regulations, this would delay or prevent both the development of our product candidates and the availability of any potential commercial product.

If we lose our relationship with any one or more of these parties, we could experience a significant delay in both identifying another comparable provider and then contracting for its services. We may be unable to retain an alternative provider on reasonable terms, if at all. Even if we locate an alternative provider, it is likely that this provider may need additional time to respond to our needs and may not provide the same type or level of service as the original provider. In addition, any provider that we retain will be subject to applicable FDA current Good Laboratory Practices (“cGLP”), current Good Manufacturing Practices (“cGMP”) and current Good Clinical Practices (“cGCP”), and comparable foreign standards. We do not have control over compliance with these regulations by these providers. Consequently, if these practices and standards are not adhered to by these providers, the development and commercialization of our product candidates could be delayed. If any of the foregoing risks are realized, our business, financial condition and results of operations could be materially adversely affected.

Because we have limited manufacturing experience, we depend on third-party manufacturers to manufacture our product, product candidates and the materials for our product candidates. Often, especially early in the development and commercialization process, we have only one source for manufacturing. If we cannot rely on existing third-party manufacturers, we will be required to incur significant costs and potential delays in finding new third-party manufacturers.

We have limited manufacturing experience and only a small scale manufacturing facility. We currently rely upon a very limited number of third-party manufacturers to manufacture the materials required for our product, product candidates and most of the preclinical and clinical quantities of our product candidates. We depend on these third-party manufacturers to perform their obligations in a timely manner and in accordance with applicable governmental regulations. Our third-party manufacturers, which may be the only manufacturer we have engaged for a particular product, may encounter difficulties with meeting our requirements including but not limited to problems involving:

- inconsistent production yields;
- product liability claims or recalls of commercial product;
- difficulties in scaling production to commercial and validation sizes;
- interruption of the delivery of materials required for the manufacturing process;
- scheduling of plant time with other vendors or unexpected equipment failure;
- potential catastrophes that could strike their facilities or have an effect on infrastructure;
- potential impurities in our drug substance or products that could affect availability of product for our clinical trials or future commercialization;
- poor quality control and assurance or inadequate process controls; and
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lack of compliance or cooperation with regulations and specifications or requests set forth by the FDA or other foreign regulatory agencies, particularly associated with RAPIVAB, BCX7353, galidesivir and our early stage compounds.

These contract manufacturers may not be able to manufacture the materials required for our product candidates at a cost or in quantities necessary to make them commercially viable. We also have no control over whether third-party manufacturers breach their agreements with us or whether they may terminate or decline to renew agreements with us. To date, our third-party manufacturers have met our manufacturing requirements, but they may not continue to do so. Furthermore, changes in the manufacturing process or procedure, including a change in the location where the drug is manufactured or a change of a third-party manufacturer, may require prior review and approval in accordance with the FDA's cGMP and comparable foreign requirements. This review may be costly and time-consuming and could delay or prevent the launch of a product. The FDA or similar foreign regulatory agencies may at any time implement new standards, or change their interpretation and enforcement of existing standards for manufacture, packaging or testing of products. If we or our contract manufacturers are unable to comply, we or they may be subject to regulatory action, civil actions or penalties any of which could be costly to the Company and could result in a delay or shortage of product.

If we are unable to maintain current manufacturing or other contract relationships, or enter into new agreements with additional manufacturers on commercially reasonable terms, or if there is poor manufacturing performance or failure to comply with any regulatory agency on the part of any of our third-party manufacturers, we may not be able to complete development of, seek timely approval of, or market, our product candidates.

Our raw materials, drug substances, and product candidates are manufactured by a limited group of suppliers, including some at a single facility. If any of these suppliers were unable to produce these items, this could significantly impact our supply of product candidate material for further preclinical testing and clinical trials.

We face intense competition, and if we are unable to compete effectively, the demand for our products, if any, may be reduced.

The biotechnology and pharmaceutical industries are highly competitive and subject to rapid and substantial technological change. There are many companies seeking to develop products for the same indications that we currently target. Our competitors in the United States and elsewhere are numerous and include, among others, major multinational pharmaceutical and chemical companies and specialized biotechnology firms. Most of these competitors have greater resources than we do, including greater financial resources, larger research and development staffs and more experienced marketing and manufacturing organizations. In addition, most of our competitors have greater experience than we do in conducting clinical trials and obtaining FDA and other regulatory approvals. Accordingly, our competitors may succeed in obtaining FDA or other regulatory approvals of product candidates more rapidly than we do. Companies that complete clinical trials, obtain required regulatory approvals, and commence commercial sale of their drugs before we do may achieve a significant competitive advantage, including patent and FDA exclusivity rights that would delay our ability to market products. We face, and will continue to face, competition in the licensing of potential product candidates for desirable disease targets licensing of desirable product candidates, and development and marketing of our product candidates from academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies. Competition may also arise from, among other things:

- other drug development technologies;
- methods of preventing or reducing the incidence of disease, including vaccines; and
- new small molecule or other classes of therapeutic agents.

Developments by others may render our product candidates or technologies obsolete or noncompetitive.

We and our partners are performing research on or developing products for the treatment of several disorders including HAE and recurrent/refractory peripheral T-cell lymphoma, as well as broad spectrum antivirals that may be developed as medical countermeasures. We expect to encounter significant competition for any of the pharmaceutical products we plan to develop. Companies that complete clinical trials, obtain required funding or government support, obtain required regulatory approvals and commence commercial sales or stockpiling orders of their products before their competitors may achieve a significant competitive advantage. Such is the case with the current neuraminidase inhibitors marketed by GSK and Roche for influenza; CINRYZE[®], KALBITOR[®] and FIRAZYR[®], marketed by Shire Pharmaceuticals, Inc. for HAE; and BERINERT[®], marketed by CSL for HAE. Therapeutic products with potentially promising data to treat Ebola include Mapp Biopharmaceutical, Inc.'s ZMapp (antibody-based) and Gilead Sciences, Inc.'s product currently under development (small molecule), both of which have been used in Ebola infected patients.

Further, several pharmaceutical and biotechnology firms, including major pharmaceutical companies and specialized structure-based drug design companies, have announced efforts in the field of structure-based drug design and molecules in development in the fields of HAE and in other therapeutic areas where we have discovery and development efforts ongoing. If one or more of our competitors' products or programs are successful, the market for our products may be reduced or eliminated.

Compared to us, many of our competitors and potential competitors have substantially greater:

- capital resources;
- research and development resources, including personnel and technology;
- regulatory experience;
- preclinical study and clinical testing experience;
- manufacturing and marketing experience; and
- production facilities.

Any of these competitive factors could impede our funding efforts, render technology and product candidates noncompetitive or eliminate or reduce demand for our product candidates.

We face risks related to our government-funded programs; if BARDA/HHS or NIAID/HHS were to eliminate, reduce or delay funding from our contracts, this would have a significant negative impact on the programs associated with such funding and could have a significant negative impact on our revenues and cash flows.

Our projections of revenues and incoming cash flows are substantially dependent upon BARDA/HHS and NIAID/HHS reimbursement for the costs related to our galidesivir program. If BARDA/HHS or NIAID/HHS were to eliminate, reduce or delay the funding for these programs or disallow some of our incurred costs, we would have to obtain additional funding for continued development or regulatory registration for these product candidates or significantly reduce or stop the development effort.

In contracting with BARDA/HHS and NIAID/HHS, we are subject to various U.S. Government contract requirements, including general clauses for a cost-reimbursement research and development contract, which may limit our reimbursement or if we are found to be in violation could result in contract termination. If the U.S. Government terminates any of its contracts with us for its convenience, or if we default by failing to perform in accordance with the contract schedule and terms, significant negative impact on our cash flows and operations could result.

Our government contracts with BARDA/HHS and NIAID/HHS have special contracting requirements, which create additional risks of reduction or loss of funding.

We have completed work under a contract with BARDA/HHS for the development of our neuraminidase inhibitor, RAPIVAB. We also have entered into contracts with BARDA/HHS and NIAID/HHS for the development of galidesivir as a treatment for diseases caused by RNA pathogens, including Marburg virus disease and Ebola virus disease. In contracting with these government agencies, we are subject to various U.S. Government contract requirements, including general clauses for a cost-reimbursement research and development contract, which may limit our reimbursement or, if we are found to be in violation, could result in contract termination.

U.S. Government contracts typically contain a number of extraordinary provisions that would not typically be found in commercial contracts and which may create a disadvantage and additional risks to us as compared to competitors that do not rely on U.S. Government contracts. These risks include the ability of the U.S. Government to unilaterally:

- terminate or reduce the scope of our contract with or without cause;
- interpret relevant regulations (federal acquisition regulation clauses);
- require performance under circumstances which may not be favorable to us;
- require an in process review where the U.S. Government will review the project and its options under the contract;

- control the timing and amount funding, which impacts the development progress of our programs; and
- audit and object to our contract-related costs and fees, including allocated indirect costs.

Our government contracts with BARDA/HHS and NIAID/HHS have termination and audit provisions which create additional risks to us.

The U.S. Government may terminate its contracts with us either for its convenience or if we default by failing to perform in accordance with the contract schedule and terms. Termination for convenience provisions generally enable us to recover only our costs incurred or committed, and settlement expenses and profit on the work completed prior to termination. Termination does not permit these recoveries under default provisions. In the event of termination or upon expiration of a contract, the U.S. Government may dispute wind-down and termination costs and may question prior expenses under the contract and deny payment of those expenses. Should we choose to challenge the U.S. Government for denying certain payments under a contract, such a challenge could subject us to substantial additional expenses which we may or may not recover. Further, if the U.S. Government terminates its contracts with us for its convenience, or if we default by failing to perform in accordance with the contract schedule and terms, significant negative impact on our cash flows and operations could result.

As a U.S. Government contractor, we are required to comply with applicable laws, regulations and standards relating to our accounting practices and are subject to periodic audits and reviews. As part of any such audit or review, the U.S. Government may review the adequacy of, and our compliance with, our internal control systems and policies, including those relating to our purchasing, property, estimating, compensation and management information systems. Audits conducted by the U.S. Government for the completed BARDA/HHS peramivir contract have been performed and concluded through fiscal 2009; all subsequent fiscal years are still open and auditable. Audits under the active BARDA/HHS and NIAID/HHS galidesivir contracts may occur at the election of the U.S. Government and have been concluded through fiscal 2013. Based on the results of its audits, the U.S. Government may adjust our contract-related costs and fees, including allocated indirect costs. This adjustment could impact the amount of revenues reported on a historic basis and could impact our cash flows under the contracts prospectively. In addition, in the event BARDA/HHS or NIAID/HHS determines that certain costs and fees were unallowable or determines that the allocated indirect cost rate was higher than the actual indirect cost rate, BARDA/HHS or NIAID/HHS would be entitled to recoup any overpayment from us as a result. In addition, if an audit or review uncovers any improper or illegal activity, we may be subject to civil and criminal penalties and administrative sanctions, including termination of our contracts, forfeiture of profits, suspension of payments, fines and suspension or prohibition from doing business with the U.S. Government. We could also suffer serious harm to our reputation if allegations of impropriety were made against us. In addition, under U.S. Government purchasing regulations, some of our costs may not be reimbursable or allowed under our contracts. Further, as a U.S. Government contractor, we are subject to an increased risk of investigations, criminal prosecution, civil fraud, whistleblower lawsuits and other legal actions and liabilities as compared to private sector commercial companies.

If we fail to reach milestones or to make annual minimum payments or otherwise breach our obligations under our license agreements, our licensors may terminate our agreements with them and seek additional remedies.

If we are unable or fail to meet payment obligations, performance milestones relating to the timing of regulatory filings, product supply obligations, post approval commitments for RAPIVAB, or development and commercial diligence obligations; are unable or fail to make milestone payments or material data use payments in accordance with applicable provisions; or fail to pay the minimum annual payments under our respective licenses, our licensors may terminate the applicable license or seek other available remedies. As a result, our development of the respective product candidate or commercialization of the product would cease.

If we fail to obtain additional financing or acceptable partnership arrangements, we may be unable to complete the development and commercialization of our product candidates or continue operations.

As our programs advance, our costs are likely to increase. Our current and planned discovery activities, pre-clinical and clinical trials, the related development, manufacturing, regulatory approval process requirements, and the additional personnel resources and testing required for supporting the development of our product candidates will consume significant capital resources. Our expenses, revenues and cash utilization rate could vary significantly depending on many factors, including: our ability to raise additional capital; the development progress of our collaborative agreements for our product candidates; the amount of funding we receive from NIAID/HHS and BARDA/HHS for galidesivir or from other new partnerships with third parties for the development of our product candidates, including BCX7353 and our other rare disease product candidates; the commercial success of peramivir achieved by our partners; the amount or profitability of any orders for peramivir or galidesivir by any government agency or other party; the progress and results of our current and proposed clinical trials for our most advanced product candidates, including BCX7353 and our other rare disease product candidates; the progress made in the manufacture of our lead products and the progression of our other programs.

We expect that we will be required to raise additional capital to complete the development and commercialization of our current product candidates and we may seek to raise capital at any time. Additional funding, whether through additional sales of securities, additional borrowings, or collaborative arrangements with partners, including governmental agencies in general and from any BARDA/HHS or NIAID/HHS contract specifically, may not be available when needed or on terms acceptable to us. The issuance of preferred or common stock or convertible securities, with terms and prices significantly more favorable than those of the currently outstanding common stock, could have the effect of diluting or adversely affecting the holdings or rights of our existing stockholders. Additional borrowings may subject us to more restrictive covenants than are currently applicable to us under the Senior Credit Facility. In addition, collaborative arrangements may require us to transfer certain material rights to such corporate partners. Insufficient funds or lack of an acceptable partnership may require us to delay, scale-back or eliminate certain of our research and development programs.

In order to continue future operations and continue our drug development programs, we will be required to raise additional capital. In addition to seeking strategic partnerships, transactions and government funding, we may decide to access the equity or debt markets, incur additional borrowings, or seek other sources to meet liquidity needs. Our ability to raise additional capital may be limited and may greatly depend upon the success of ongoing development related to our current drug development programs, including post approval studies for RAPIVAB, the progress, timeline and ultimate outcome of our kallikrein inhibitor, including the BCX7353 program (including, but not limited to, formulation progress, phase 3 trials, long-term human safety studies, and the timing of carcinogenicity or other required studies), the progress our other rare disease product candidates, funding for and continued successful development of galidesivir, and the progress of our early discovery programs. In addition, constriction and volatility in the equity and debt markets may restrict our future flexibility to raise capital when such needs arise. Furthermore, we have exposure to many different industries, financing partners and counterparties, including commercial banks, investment banks and partners (which include investors, licensing partners, and the U.S. Government) which may be unstable or may become unstable in the current economic and political environment. Any such instability may impact these parties' ability to fulfill contractual obligations to us or they might limit or place burdensome conditions upon future transactions with us. Also, it is possible that suppliers may be negatively impacted. Any such unfavorable outcomes in our current programs or unfavorable economic conditions could place severe downward pressure on the price of our common stock and may decrease opportunities to raise capital in the capital or credit markets, and further could reduce the return available on invested corporate cash, which, if severe and sustained, could have a material and adverse impact on our results of operations and cash flows and limit our ability to continue development of our product candidates.

If we fail to successfully commercialize or establish collaborative relationships to commercialize certain of our product candidates, or if any partner terminates or fails to perform its obligations under agreements with us, potential revenues from commercialization of our product candidates could be reduced, delayed or eliminated.

Our business strategy is to increase the asset value of our product candidate portfolio. We believe this is best achieved by retaining full product rights or through collaborative arrangements with third parties as appropriate. As needed, potential third-party relationships could include preclinical development, clinical development, regulatory approval, marketing, sales and distribution of our product candidates.

Currently, we have established collaborative relationships with Mundipharma for the development and commercialization of forodesine and with each of Shionogi and Green Cross for the development and commercialization of peramivir, in Japan, Taiwan and South Korea. Most recently we have established a collaborative relationship with Seqirus UK Limited for RAPIVAB on a worldwide basis other than Israel, Japan, Korea and Taiwan. The process of establishing and implementing collaborative relationships is difficult, time-consuming and involves significant uncertainty, including:

- our partners may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical results, including post approval clinical commitments, a change in business strategy, a change of control or other reasons;
- our contracts for collaborative arrangements may expire;
- our partners may choose to pursue alternative technologies, including those of our competitors;
- we may have disputes with a partner that could lead to litigation or arbitration;
- we do not have day to day control over the activities of our partners and have limited control over their decisions;
- our ability to generate future event payments and royalties from our partners depends upon their abilities to establish the safety and efficacy of our product candidates, obtain regulatory approvals and achieve market acceptance of products developed from our product candidates;
- we or our partners may fail to properly initiate, maintain or defend our intellectual property rights, where applicable, or a party may utilize our proprietary information in such a way as to invite litigation that could jeopardize or potentially invalidate our proprietary information or expose us to potential liability;
- we or our partners may not devote sufficient capital or resources towards our product candidates; and
- we or our partners may not comply with applicable government regulatory requirements.

If we or our partners fail to fulfill our responsibilities in a timely manner, or at all, our commercialization efforts related to that collaboration could be reduced, delayed or terminated, or it may be necessary for us to assume responsibility for activities that would otherwise have been the responsibility of our partner. If we are unable to

establish and maintain collaborative relationships on acceptable terms, we may have to delay or discontinue further development of one or more of our product candidates, undertake commercialization activities at our own expense or find alternative sources of funding. Any delay in the development or commercialization of our product candidates would severely affect our business, because if our product candidates do not progress through the development process or reach the market in a timely manner, or at all, we may not receive additional future event payments and may never receive milestone, product sales or royalty payments.

We do not have a great deal of experience in commercializing our products or technologies, and our future revenue generation is uncertain.

We do not have a great deal of experience in commercializing our product candidates or technologies. We currently have limited marketing and commercial capability, no direct or third-party sales force and limited distribution capabilities. We may be unable to establish or sufficiently increase these capabilities for products we currently, or plan to, commercialize. In addition, our revenue from collaborative agreements may be dependent upon the status of our preclinical and clinical programs. If we fail to advance these programs to the point of being able to enter into successful collaborations, we will not receive any potential future event or other collaborative payments.

Our ability to receive revenue from products we commercialize presents several risks, including:

- we or our collaborators may fail to successfully complete clinical trials, or satisfy post-marketing commitments, sufficient to obtain and keep FDA marketing approval;

- many competitors are more experienced and have significantly more resources, and their products could reach the market faster, be more cost effective or have a better efficacy or tolerability profile than our product candidates;
- we may fail to employ a comprehensive and effective intellectual property strategy, which could result in decreased commercial value of our Company and our products;
- we may fail to employ a comprehensive and effective regulatory strategy, which could result in a delay or failure in commercialization of our products;
- our ability to successfully commercialize our products is affected by the competitive landscape, which cannot be fully known at this time;
- reimbursement is constantly changing, which could greatly affect usage of our products; and
- future revenue from product sales would depend on our ability to successfully complete clinical studies, obtain regulatory approvals, and manufacture, market and commercialize our approved drugs.

Commercialization of peramivir by our partners is subject to the potential commercialization risks described herein and numerous additional risks. Any potential revenue benefits to us in the form of milestone payments, royalties or other consideration are highly speculative.

Commercialization success of peramivir is uncertain and is subject to all the risks and uncertainties disclosed in our other risk factors relating to drug development and commercialization. In addition, commercialization of peramivir products is subject to further risks and may be negatively impacted by a number of factors, including, but not limited to, the following:

- peramivir may not prove to be adequately safe and effective for market approval in markets other than the United States, Japan, Korea and Taiwan;
- necessary funding for post-marketing commitments and further development of peramivir may not be available timely, at all, or in sufficient amounts;
- flu prevention or pandemic treatment concerns may not materialize at all, or in the near future;
- advances in flu vaccines or other antivirals, including competitive i.v. antivirals, could substantially replace potential demand for peramivir;
- a limited number of governmental entities are expected to be the primary potential stockpiling customers for RAPIVAB and if we are not successful at marketing peramivir to these entities for any reason, we will not receive substantial revenues from stockpiling orders;
- government and third party payors may not provide sufficient coverage or reimbursement which would negatively impact the demand for peramivir;

- we may not be able to supply commercial material to our partners and our partners may not be able to maintain or establish sufficient and acceptable commercial manufacturing, either directly or through third-party manufacturers;
- the commercial demand and acceptance for peramivir by healthcare providers and by patients may not be sufficient to result in substantial revenues of peramivir to our partners and may result in little to no milestones or royalties to us;
- effectiveness of marketing efforts for peramivir by our partners;
- market satisfaction with existing alternative therapies;
- perceived efficacy relative to other available therapies;
- disease prevalence;
- cost of treatment;
- pricing and availability of alternative products;
- marketing and sales activities of competitors;

- shifts in the medical community to new treatment paradigms or standards of care; and
- relative convenience and ease of administration.

We are subject to various federal and state laws related to RAPIVAB and other products under development and, if we or our partners do not comply with these regulations, we could face substantial penalties.

Our or our partners' activities related to RAPIVAB, or any of our other products under development and following their regulatory approval, are subject to regulatory and law enforcement authorities in addition to the FDA, including the Federal Trade Commission, the Department of Justice, and state and local governments. In the case of our collaboration with SUL, although SUL is responsible for RAPIVAB marketing and commercialization efforts, we continue to carry certain risks associated with RAPIVAB because we hold the RAPIVAB NDA. For example, we are responsible for reporting adverse drug experiences, we have responsibility for certain post-approval studies, we may have responsibilities and costs related to a recall or withdrawal of RAPIVAB from sale, we may incur liability associated with RAPIVAB manufacturing contracted by us or in support of any of our partners, we are required to maintain records and provide data and reports to regulatory agencies related to RAPIVAB (e.g. risk evaluation and mitigation strategies, track and trace requirements, adverse events), and we may incur certain promotional regulatory and government pricing risks, all of which could have a material adverse impact on our operations and financial condition. In addition, we are now subject to the federal physician sunshine act and certain similar legislation in various states. We are subject to various federal and state laws pertaining to health care "fraud and abuse," including both federal and state anti-kickback laws. Although we seek to comply with these statutes, it is possible that our practices, or those of our distributors, might be challenged under anti-kickback or similar laws. Violations of the physician sunshine act and similar state legislation or the fraud and abuse laws may be punishable by civil or criminal sanctions, including fines and civil monetary penalties, and future exclusion from participation in government healthcare programs.

We have a number of outstanding post-marketing commitments to the FDA that we retain, despite our partnership with SUL, which we may not complete successfully or on time for any number of reasons, including but not limited to lack of funds to complete the studies and insufficient interest by appropriate sites, investigators or study subjects. For example, as a condition of the approval of RAPIVAB, we are required to complete a pediatric patient study of RAPIVAB and to submit the final results of this clinical trial to the FDA. Depending on the outcome of this clinical trial, we may be unable to expand the indication for RAPIVAB or we may be required to include specific warnings or limitations on dosing this product, which could negatively impact sales of RAPIVAB and negatively impact our relationship with our partner. We may be subject to penalties if we fail to comply with post-approval legal and regulatory requirements and our products could be subject to continual recordkeeping and reporting requirements, review and periodic inspections by the FDA and other regulatory bodies. Regulatory approval of a product may be subject to limitations on the indicated uses for which the product may be marketed or to the other restrictive conditions of approval that limit our ability to promote, sell or distribute a product. Furthermore, the approval of RAPIVAB and any other future product candidates may be subject to requirements for costly post-marketing testing and surveillance to monitor its safety or efficacy.

Advertising and promotion are subject to stringent FDA rules and oversight and as the holder of the NDA we may be held responsible for any advertising and promotion conducted by our partner that is not in compliance with the rules and regulations. In particular, the claims in all promotional materials and activities must be consistent with the FDA approvals for approved products, and must be appropriately substantiated and fairly balanced with information on the safety risks and limitations of the products. Adverse event information concerning approved products must be reviewed and as the NDA holder of RAPIVAB we are required to make expedited and periodic adverse event reports to the FDA and other regulatory authorities.

In addition, the research, manufacturing, distribution, sale and promotion of products are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services, other divisions of the U.S. Department of Health and Human Services, the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice, and state and local governments. Until we can successfully transfer the pricing responsibilities to our partner, we remain responsible for pricing and rebate programs. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Veterans Health Care Act of 1992, as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

If our operations with respect to RAPIVAB or our other products that are subject to healthcare laws and regulations are found to be in violation of any of the healthcare fraud and abuse laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with all applicable federal and state fraud and abuse laws may be costly.

We and our partners may be subject to new legislation, regulatory proposals and healthcare payor initiatives that may increase our costs of compliance and adversely affect our or our partners' ability to market our products, including RAPIVAB, obtain collaborators and raise capital.

The Patient Protection and Affordable Care Act, or PPACA, made extensive changes to the delivery of health care in the U.S. The PPACA includes numerous provisions that affect pharmaceutical companies, some of which became effective immediately and others of which will be taking effect over the next several years. For example, the PPACA seeks to expand health care coverage to the uninsured through private health insurance reforms and an expansion of Medicaid. The PPACA will also impose substantial costs on pharmaceutical manufacturers, such as an increase in liability for rebates paid to Medicaid, new drug discounts that must be offered to certain enrollees in the Medicare prescription drug benefit, an annual fee imposed on all manufacturers of brand prescription drugs in the U.S., and an expansion of an existing program requiring pharmaceutical discounts to certain types of hospitals and federally subsidized clinics. The PPACA also contains cost containment measures that could reduce reimbursement levels for health care items and services generally, including pharmaceuticals. It also will require reporting and public disclosure of payments and other transfers of value provided by pharmaceutical companies to physicians and teaching hospitals. We cannot predict what effect the PPACA or other healthcare reform initiatives that may be adopted in the future will have on our business. Further, it remains unclear whether there will be any changes made to provisions of the PPACA or other health care laws through acts of Congress in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care services to contain or reduce costs of health care could result in decreased net revenues from our pharmaceutical products and decrease potential returns from our development efforts. In addition, pharmaceutical and device manufacturers will also be required to report and disclose investment interests held by physicians and their immediate family members during the preceding calendar year. Failure to submit required information may result in civil monetary penalties for payments, transfers of value or ownership or investment interests not reported in an annual submission. Compliance with the PPACA and state laws with similar provisions is difficult and time consuming, and companies that do not comply with these state laws face civil penalties. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Such a challenge could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In addition, there have been a number of other legislative and regulatory proposals aimed at changing the pharmaceutical industry. In particular, legislation has been enacted in certain states and proposed at a federal level that requires development of an electronic pedigree to track and trace each prescription drug at the saleable unit level through the distribution system. Compliance with these electronic pedigree requirements may increase our operational expenses and impose significant administrative burdens. In addition, our compliance may be deemed insufficient and we could face a material adverse effect on our business, financial condition, results of operations and growth prospects. As a result of these and other new proposals, we may determine to change our current manner of operation, provide additional benefits or change our contract arrangements, any of which could have a material adverse effect on our business, financial condition and results of operations.

Managed care organizations are increasingly challenging the prices charged for medical products and services and, in some cases, imposing restrictions on the coverage of particular drugs. Many managed care organizations negotiate the price of medical services and products and develop formularies which establish pricing and reimbursement levels. Exclusion of a product from a formulary can lead to its sharply reduced usage in the managed care organization's

patient population. The process for obtaining coverage can be lengthy and costly, and we expect that it could take several months before a particular payor initially reviews our product and makes a decision with respect to coverage. For example, third-party payors may require cost-benefit analysis data from us in order to demonstrate the cost-effectiveness of RAPIVAB or any other product we might bring to market. For any individual third-party payor, we may not be able to provide data sufficient to gain reimbursement on a similar or preferred basis to competitive products, or at all which may have a material adverse effect on our business, financial condition and results of operations.

There are risks related to the potential government use or sale of peramivir (RAPIVAB).

United States Government use or sale of RAPIVAB in emergency situations, or otherwise, may result in the use of RAPIVAB outside of its approved use. To the extent that RAPIVAB is used as a treatment for influenza by the U.S. Government or peramivir by any other government entity, there can be no assurance that it will prove to be generally safe, well-tolerated and effective. Such government use of peramivir may create certain liabilities for us or our partners in the case of government use outside of the U.S. There is no assurance that we or our manufacturers will be able to fully meet the demand for peramivir in the event of additional orders. Further, we may not achieve a favorable price for additional orders of RAPIVAB in the U.S. or peramivir in any other country. Our competitors may develop products that could compete with or replace peramivir. We may face competition in markets where we have no existing intellectual property protection or are unable to successfully enforce our intellectual property rights.

There is no assurance that the non-U.S. partnerships that we have entered into for peramivir will result in any order for peramivir in those countries. There is no assurance that peramivir will be approved for any use or will achieve market approval in additional countries. In the event that any emergency use or market approval is granted, there is no assurance that any government order or commercialization of peramivir in any countries will be substantial or will be profitable to us. In addition, the sale of peramivir, emergency use or other use of peramivir in any country may create certain liabilities for us and our partners.

If we or our partners do not obtain and maintain governmental approvals for our product candidates under development, we or our partners will not be able to sell these potential products, which would significantly harm our business because we will receive no revenue.

We or our partners must obtain regulatory approval before marketing or selling our future product candidates. If we or our partners are unable to receive regulatory approval and do not market or sell our future product candidates, we will never receive any revenue from such product sales. In the United States, we or our partners must obtain FDA approval for product candidates that we intend to commercialize. The process of preparing for and obtaining FDA approval may be lengthy and expensive, and approval is never certain. Products distributed abroad are also subject to foreign government regulation and export laws of the United States. Because of the risks and uncertainties in biopharmaceutical development, our product candidates could take a significantly longer time to gain regulatory approval than we expect or may never gain approval. If the FDA delays regulatory approval of our product candidates, our management's credibility, our value and our operating results may suffer. Even if the FDA or foreign regulatory agencies approve a product candidate, the approval may limit the indicated uses for a product candidate and/or may require post-approval studies.

The FDA regulates, among other things, the record keeping and storage of data pertaining to potential pharmaceutical products. We currently store most of our preclinical research data, our clinical data and our manufacturing data at our facility. While we do store duplicate copies of most of our clinical data offsite and a significant portion of our data is included in regular backups of our systems, we could lose important data if our facility incurs damage, or if our vendor data systems fail, suffer damage or are destroyed. If we receive approval to market our potential products, whether in the United States or internationally, we will continue to be subject to extensive regulatory requirements. These requirements are wide ranging and govern, among other things:

- adverse drug experience reporting regulations;
- product promotion;
- product manufacturing, including good manufacturing practice requirements; and
- product changes or modifications.

Our failure to comply with existing or future regulatory requirements, or our loss of, or changes to, previously obtained approvals, could have a material adverse effect on our business because we will not receive product or royalty revenues if we or our partners do not receive approval of our products for marketing.

Royalties and milestone payments from Shionogi under our license agreement with Shionogi (the "Shionogi Agreement") will be required to be used by Royalty Sub to service its obligations under its Pharma Notes, and generally will not be available to us for other purposes until Royalty Sub has repaid in full its obligations under the Pharma Notes.

In March 2011, our wholly-owned subsidiary Royalty Sub issued \$30.0 million in aggregate principal amount of PhaRMA Notes. The PhaRMA Notes are secured principally by (i) certain royalty and milestone payments under the Shionogi Agreement, pursuant to which Shionogi licensed from us the rights to market peramivir in Japan and Taiwan, (ii) rights to certain payments under a Japanese yen/U.S. dollar foreign currency hedge arrangement put into place by us in connection with the issuance of the PhaRMA Notes and (iii) the pledge by us of our equity interest in Royalty Sub. Payments from Shionogi to us under the Shionogi Agreement will generally not be available to us for other purposes until Royalty Sub has repaid in full its obligations under the PhaRMA Notes. Accordingly, these funds will be required to be dedicated to Royalty Sub's debt service and not available to us for product development or other purposes. As of September 1, 2014, the payments from Shionogi were insufficient for Royalty Sub to service its obligations under the PhaRMA Notes, resulting in an event of default with respect to the PhaRMA Notes. As a result of this event of default, the holders of the PhaRMA Notes may be able to pursue acceleration of the PhaRMA Notes and foreclose on the collateral securing the PhaRMA Notes and our equity interest in Royalty Sub and may exercise other remedies available to them under the indenture or other documents related to the PhaRMA Notes. In such event, we may not realize the benefit of future royalty payments that might otherwise accrue to us following repayment of the PhaRMA Notes, we may incur legal costs and we might otherwise be adversely affected.

Because an event of default has occurred under the PhaRMA Notes, the holders of the PhaRMA Notes may be able to pursue acceleration of the PhaRMA Notes and foreclose on the collateral securing the PhaRMA Notes and our equity interest in Royalty Sub, in which case we may not realize the benefit of future royalty payments that might otherwise accrue to us following repayment of the PhaRMA Notes and we could otherwise be adversely affected.

Royalty Sub's ability to service its payment obligations in respect of the PhaRMA Notes, and our ability to benefit from our equity interest in Royalty Sub, is subject to numerous risks. Royalty Sub's ability to service the PhaRMA Notes may be adversely affected by, among other things, changes in or any termination of our relationship with Shionogi, reimbursement, regulatory, manufacturing and/or intellectual property issues, product returns, product recalls, product liability claims and allegations of safety issues, as well as other factors. As Royalty Sub has been unable to service its obligations under the PhaRMA Notes and an event of default has occurred under the PhaRMA Notes, the holders of the PhaRMA Notes may be able to pursue acceleration of the PhaRMA Notes and foreclose on the collateral securing the PhaRMA Notes and our equity interest in Royalty Sub and may exercise other remedies available to them under the indenture or other documents related to the PhaRMA Notes. In such event, we may not realize the benefit of future royalty payments that might otherwise accrue to us following repayment of the PhaRMA Notes, we may incur legal costs and we might otherwise be adversely affected.

We may be required to pay significant premiums under the foreign currency hedge arrangement entered into by us in connection with the issuance of the PhaRMA Notes. In addition, because our potential obligations under the foreign currency hedge are marked to market, we may experience additional quarterly volatility in our operating results and cash flows attributable to the foreign currency hedge arrangement.

In connection with the issuance by Royalty Sub of the PhaRMA Notes, we entered into a foreign currency hedge arrangement to hedge certain risks associated with changes in the value of the Japanese yen relative to the U.S. dollar. Under the foreign currency hedge agreement, we may be required to pay an annual premium in the amount of \$2.0 million in each May continuing through May 2020. Such payment will be required if, in May of the relevant year, the spot rate of exchange for Japanese yen-U.S. dollars (determined in accordance with the foreign currency hedge arrangement) is such that the U.S. dollar is worth 100 yen or less. We will be required to mark-to-market our potential obligations under the currency hedge and post cash collateral, which may cause us to experience additional quarterly volatility in our operating results and cash flows as a result. Additionally, we may be required to pay significant premiums or a termination fee under the foreign currency hedge agreement entered into by us in connection with the issuance of the PhaRMA Notes. We are required to maintain a foreign currency hedge at 100 yen per dollar under the agreements governing the PhaRMA Notes.

Our Senior Credit Facility contains restrictions that limit our flexibility in operating our business. We may be required to make a prepayment or repay the outstanding indebtedness earlier than we expect if a prepayment event or an event of default occurs, including a material adverse change with respect to us, which could have a material adverse effect on our business.

The Senior Credit Facility contains various covenants that limit our ability to engage in specified types of transactions. These covenants limit our ability to, among other things:

- convey, sell, lease, license, transfer or otherwise dispose of certain parts of our business or property;
- change the nature of our business;
- liquidate or dissolve;
- enter into certain change in control or acquisition transactions;
- incur or assume certain debt;
- grant certain types of liens on our assets;
- modify, liquidate or transfer assets in certain collateral accounts;
- pay dividends or make certain distributions to our stockholders;

- make certain investments;
- enter into material transactions with affiliates; and
- modify existing debt or collaboration arrangements.

The restrictive covenants contained in the Senior Credit Facility could cause us to be unable to pursue business opportunities that we or our stockholders may consider beneficial without the lender's permission or without repaying all Senior Credit Facility obligations.

A breach of any of these covenants could result in an event of default under the Senior Credit Facility. An event of default will also occur if, among other things, a material adverse change in our business, operations or condition occurs, which could potentially include negative results in clinical trials, or a material impairment of the prospect of our repayment of any portion of the amounts we owe under the Senior Credit Facility occurs. In the case of a continuing event of default under the agreement, the lender could elect to declare all amounts outstanding to be immediately due and payable, proceed against the collateral in which we granted to the lender a security interest under the Senior Credit Facility, or otherwise exercise the rights of a secured creditor. Amounts outstanding under the Senior Credit Facility are secured by substantially all of our assets and those of our subsidiaries, excluding certain specified assets but including proceeds from those assets.

If we fail to adequately protect or enforce our intellectual property rights or secure rights to patents of others, the value of those rights would diminish.

Our success will depend in part on our ability and the abilities of our partners to obtain, protect and enforce viable intellectual property rights including but not limited to trade name, trademark and patent protection for our Company and its products, methods, processes and other technologies we may license or develop, to preserve our trade secrets, and to operate without infringing the proprietary rights of third parties both domestically and abroad. The patent position of biotechnology and pharmaceutical companies is generally highly uncertain, involves complex legal and factual questions and has recently been the subject of much litigation. Neither the United States Patent and Trademark Office (“USPTO”), the Patent Cooperation Treaty offices, nor the courts of the United States and other jurisdictions have consistent policies nor predictable rulings regarding the breadth of claims allowed or the degree of protection afforded under many biotechnology and pharmaceutical patents. Further, we may not have worldwide patent protection for all of our product candidates and our intellectual property rights may not be legally protected or enforceable in all countries throughout the world. In some jurisdictions, some of our product candidates in certain programs, including our HAE program, may have short or no composition of matter patent life and we may therefore rely on orphan drug exclusivity or data exclusivity. There can be no assurance that we will obtain orphan drug exclusivity or data exclusivity in every jurisdiction. Further, in some jurisdictions, we may rely on formulation patents or method of use patents. Both the ability to achieve issuance and the enforcement of formulation and method of use patents can be highly uncertain and can vary from jurisdiction to jurisdiction, and such patents may therefore not adequately prevent competitors and potential infringers in some jurisdictions. The validity, scope, enforceability and commercial value of the rights protected by such patents, therefore, is highly uncertain.

We also rely on trade secrets to protect technology in cases when we believe patent protection is not appropriate or obtainable. However, trade secrets are difficult to protect. If we cannot maintain the confidentiality of our technology and other confidential information in connection with our collaborators and advisors, our ability to receive patent protection or protect our proprietary information may be imperiled.

We may be involved in lawsuits to protect or enforce our patents, the patents of our partners or our other intellectual property rights, which could be expensive, time consuming and unsuccessful.

Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming and unsuccessful. An adverse result in any litigation or defense proceeding could put one or more of our patents at risk. Our success depends in part on avoiding the infringement of other parties’ patents and other intellectual property rights as well as avoiding the breach of any licenses relating to our technologies and products. In the United States, patent applications filed in recent years are confidential for 18 months, while older applications are not published until the patent issues. As a result, avoiding patent infringement may be difficult and we may inadvertently infringe third-party patents or proprietary rights. These third parties could bring claims against us, our partners or our licensors that even if resolved in our favor, could cause us to incur substantial expenses and, if resolved against us, could additionally cause us to pay substantial damages. Further, if a patent infringement suit were brought against us, our partners or our licensors, we or they could be forced to stop or delay research, development,

manufacturing or sales of any infringing product in the country or countries covered by the patent we infringe, unless we can obtain a license from the patent holder. Such a license may not be available on acceptable terms, or at all, particularly if the third party is developing or marketing a product competitive with the infringing product. Even if we, our partners or our licensors were able to obtain a license, the rights may be nonexclusive, which would give our competitors access to the same intellectual property.

If we or our partners are unable or fail to adequately initiate, protect, defend or enforce our intellectual property rights in any area of commercial interest or in any part of the world where we wish to seek regulatory approval for our products, methods, processes and other technologies, the value of the product candidates to produce revenue would diminish. Additionally, if our products, methods, processes, and other technologies or our commercial use of such products, processes, and other technologies, including but not limited to any trade name, trademark or commercial strategy infringe the proprietary rights of other parties, we could incur substantial costs. The USPTO and the patent offices of other jurisdictions have issued to us a number of patents for our various inventions and we have in-licensed several patents from various institutions. We have filed additional patent applications and provisional patent applications with the USPTO. We have filed a number of corresponding foreign patent applications and intend to file additional foreign and U.S. patent applications, as appropriate. We have also filed certain trademark and trade name applications worldwide. We cannot assure you as to:

- the degree and range of protection any patents will afford against competitors with similar products;
- if and when patents will issue;
- if patents do issue we cannot be sure that we will be able to adequately defend such patents and whether or not we will be able to adequately enforce such patents; or
- whether or not others will obtain patents claiming aspects similar to those covered by our patent applications.

If the USPTO or other foreign patent office upholds patents issued to others or if the USPTO grants patent applications filed by others, we may have to:

- obtain licenses or redesign our products or processes to avoid infringement;
- stop using the subject matter claimed in those patents; or
- pay damages.

We may initiate, or others may bring against us, litigation or administrative proceedings related to intellectual property rights, including proceedings before the USPTO or other foreign patent office. Any judgment adverse to us in any litigation or other proceeding arising in connection with a patent or patent application could materially and adversely affect our business, financial condition and results of operations. In addition, the costs of any such proceeding may be substantial whether or not we are successful.

Our success is also dependent upon the skills, knowledge and experience, none of which is patentable, of our scientific and technical personnel. To help protect our rights, we require all employees, consultants, advisors and partners to enter into confidentiality agreements that prohibit the disclosure of confidential information to anyone outside of our company and require disclosure and assignment to us of their ideas, developments, discoveries and inventions. These agreements may not provide adequate protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of such information, and if any of our proprietary information is disclosed, our business will suffer because our revenues depend upon our ability to license or commercialize our product candidates and any such events would significantly impair the value of such product candidates.

Our failure to comply with data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.

European Union (“EU”) Member States, Switzerland and other countries have adopted data protection laws and regulation, which impose significant compliance obligations. For example, the EU Data Protection Directive, as implemented into national laws by the EU Member States, imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. Data protection authorities from the different EU Member States may interpret the EU Data Protection Directive and national laws differently, which adds to the complexity of processing personal data in the European Union, and guidance on implementation and compliance practices are often updated or otherwise revised. Our failure to comply with these laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.

We are subject to periodic litigation, which could result in losses or unexpected expenditure of time and resources.

From time to time, we may be called upon to defend ourselves against lawsuits relating to our business. Due to the inherent uncertainties in litigation, we cannot accurately predict the ultimate outcome of any such proceeding. An unfavorable outcome in any such proceeds could have an adverse impact on our business, financial condition and results of operations. If our stock price is volatile, we may become involved in securities class action lawsuits in the future. Any litigation in the future, regardless of its merits, could result in substantial costs and a diversion of management's attention and resources that are needed to successfully run our business.

We face an inherent risk of liability in the event that the use or misuse of our products results in personal injury or death and our product liability insurance coverage may be insufficient.

If the use or misuse of peramivir or any other regulatory body-approved products we or a partner may sell in the future harms people, we may be subject to costly and damaging product liability claims brought against us by consumers, healthcare providers, pharmaceutical companies, third-party payors or others. The use of our product candidates in clinical trials, including post marketing clinical studies, could also expose us to product liability claims. We cannot predict all of the possible harms or side effects that may result from the use of our products or the testing of product candidates and, therefore, the amount of insurance coverage we currently may not be adequate to cover all liabilities or defense costs we might incur. A product liability claim or series of claims brought against us could give rise to a substantial liability that could exceed our resources. Even if claims are not successful, the costs of defending such claims and potential adverse publicity could be harmful to our business.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face even greater risks upon any commercialization by us of our product candidates. We have product liability insurance covering our commercial sale of RAPIVAB and our clinical trials. Clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance or increase our existing coverage at a reasonable cost to protect us against losses that could have a material adverse effect on our business. An individual may bring a product liability claim against us if one of our products or product candidates causes, or is claimed to have caused, an injury or is found to be unsuitable for consumer use. Any product liability claim brought against us, with or without merit, could result in:

- liabilities that substantially exceed our product liability insurance, which we would then be required to pay from other sources, if available;
- an increase of our product liability insurance rates or the inability to maintain insurance coverage in the future on acceptable terms, or at all;
- withdrawal of clinical trial volunteers or patients;
- damage to our reputation and the reputation of our products, resulting in lower sales;
- regulatory investigations that could require costly recalls or product modifications;
- litigation costs; and
- the diversion of management's attention from managing our business.

Insurance coverage is increasingly more costly and difficult to obtain or maintain.

While we currently have insurance for our business, property, directors and officers, and our products insurance is increasingly more costly and narrower in scope, and we may be required to assume more risk in the future. If we are subject to claims or suffer a loss or damage in excess of our insurance coverage, we will be required to bear any loss in excess of our insurance limits. If we are subject to claims or suffer a loss or damage that is outside of our insurance coverage, we may incur significant uninsured costs associated with loss or damage that could have an adverse effect on our operations and financial position. Furthermore, any claims made on our insurance policies may impact our ability to obtain or maintain insurance coverage at reasonable costs or at all.

If our facility incurs damage or power is lost for a significant length of time, or if we incur significant cost overruns or delays in the construction of our new research facility in Birmingham, Alabama, our business will suffer.

We store clinical and stability samples at our facility that could be damaged if our facility incurs physical damage or in the event of an extended power failure. We have backup power systems in addition to backup generators to maintain power to all critical functions, but any loss of these samples could result in significant delays in our drug development process.

In addition, we store most of our preclinical and clinical data at our facilities. Duplicate copies of most critical data are secured off-site. Any significant degradation or failure of our computer systems could cause us to inaccurately calculate or lose our data. Loss of data could result in significant delays in our drug development process and any system failure could harm our business and operations.

We also face the risk that the costs and time required in connection with the construction of our new research facility in Birmingham, Alabama could exceed our current expectations. If there is a significant cost overrun or significant delay in the completion of the construction, our business, financial condition, and results of operations could be adversely affected.

A significant disruption in our information technology systems or a cyber-security breach could adversely affect our business.

We are increasingly dependent on information technology systems to operate our business. Like other companies in our industry, our networks and infrastructure may be vulnerable to cyber-attacks or intrusions, including by computer hackers, foreign governments, foreign companies or competitors, or may be breached by employee error, malfeasance or other disruption. A breakdown, invasion, corruption, destruction or interruption of critical information technology systems could negatively impact operations. If our systems are damaged, fail to function properly or otherwise become unavailable, we may incur substantial costs to repair or replace them, and we may experience loss of critical data and interruptions or delays in our ability to perform critical functions, which could adversely affect our business, financial condition or results of operations. Any compromise of our data security could also result in a violation of applicable privacy and other laws, significant legal and financial exposure, damage to our reputation, loss or misuse of the information and a loss of confidence in our data security measures, which could harm our business. There can be no assurance that our efforts to protect our data and information technology systems will prevent breakdowns or breaches in our systems, or those of third parties with which we do business, and any such events could adversely affect our business.

If we fail to retain our existing key personnel or fail to attract and retain additional key personnel, the development of our product candidates and commercialization of our products and the related expansion of our business will be delayed or stopped.

We are highly dependent upon our senior management and scientific team, the unexpected loss of whose services might impede the achievement of our development and commercial objectives. Competition for key personnel with the experience that we require is intense and is expected to continue to increase. Our inability to attract and retain the required number of skilled and experienced management, commercial, operational and scientific personnel will harm our business because we rely upon these personnel for many critical functions of our business.

If because of our use of hazardous materials, we violate any environmental controls or regulations that apply to such materials, we may incur substantial costs and expenses in our remediation efforts.

Our research and development involves the controlled use of hazardous materials, chemicals and various radioactive compounds. We are subject to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and some waste products. Accidental contamination or injury from these materials could occur. In the event of an accident, we could be liable for any damages that result and any liabilities could exceed our resources. Compliance with environmental laws and regulations or a violation of such environmental laws and regulations could require us to incur substantial unexpected costs, which would materially and adversely affect our results of operations.

Risks relating to investing in our common stock

Our existing principal stockholders hold a substantial amount of our common stock and may be able to influence significant corporate decisions, which may conflict with the interest of other stockholders.

Several of our stockholders own greater than 5% of our outstanding common stock. Our top ten stockholders own more than 50% of BioCryst and can individually, and as a group, influence our operations based upon their concentrated ownership. These stockholders, if they act together, may be able to influence the outcome of matters requiring approval of the stockholders, including the election of our directors and other corporate actions.

Our stock price has been, and is likely to continue to be, highly volatile, which could cause the value of an investment in our common stock to decline significantly.

The market prices for securities of biotechnology companies in general have been highly volatile and may continue to be highly volatile in the future. Moreover, our stock price has fluctuated frequently, and these fluctuations are often not related to our financial results. For the twelve months ended September 30, 2016, the 52-week range of the market price of our stock was from \$1.63 to \$12.88 per share. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

- announcements of technological innovations or new products by us or our competitors;
- developments or disputes concerning patents or proprietary rights;
- additional dilution through sales of our common stock or other derivative securities;
- status of new or existing licensing or collaborative agreements and government contracts;
- announcements relating to the status of our programs;
- developments and announcements regarding new and virulent strains of influenza;
- we or our partners achieving or failing to achieve development milestones;
- publicity regarding actual or potential medical results relating to products under development by us or our competitors;
- publicity regarding certain public health concerns for which we are or may be developing treatments;
- regulatory developments in both the United States and foreign countries;
- public concern as to the safety of pharmaceutical products;
- actual or anticipated fluctuations in our operating results;
- changes in financial estimates or recommendations by securities analysts;
- changes in the structure of healthcare payment systems, including developments in price control legislation;

- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- additions or departures of key personnel or members of our board of directors;
- purchases or sales of substantial amounts of our stock by existing stockholders, including officers or directors;
- economic and other external factors or other disasters or crises; and
- period-to-period fluctuations in our financial results.

Future sales and issuances of securities may dilute the ownership interests of our current stockholders and cause our stock price to decline.

Future sales of our common stock by current stockholders into the public market could cause the market price of our stock to fall. As of October 31, 2016, there were 73,758,320 shares of our common stock outstanding. We may from time to time issue securities in relation to a license arrangement, collaboration, merger or acquisition. We may also sell, for our own account, shares of common stock or other equity securities, from time to time at prices and on terms to be determined at the time of sale.

As of October 31, 2016, there were 12,585,964 stock options and restricted stock units outstanding, 2,241,126 shares available for issuance under our Amended and Restated Stock Incentive Plan, and 421,748 shares available for issuance under our Employee Stock Purchase Plan. In addition, we could also make equity compensation grants outside of our Stock Incentive Plan. The shares underlying existing stock options, restricted stock units and possible future stock options, stock appreciation rights and stock awards have been registered pursuant to registration statements on Form S-8.

If some or all of such shares are sold or otherwise issued into the public market over a short period of time, our current stockholders' ownership interests may be diluted and the value of all publicly traded shares is likely to decline, as the market may not be able to absorb those shares at then-current market prices. Additionally, such sales and issuances may make it more difficult for us to sell equity securities or equity-related securities in the future at a time and price that our management deems acceptable, or at all.

We have anti-takeover provisions in our corporate charter documents that may result in outcomes with which you do not agree.

Our board of directors has the authority to issue up to 4,800,000 shares of undesignated preferred stock and to determine the rights, preferences, privileges and restrictions of those shares without further vote or action by our stockholders. The rights of the holders of any preferred stock that may be issued in the future may adversely affect the rights of the holders of common stock. The issuance of preferred stock could make it more difficult for third parties to acquire a majority of our outstanding voting stock.

In addition, our certificate of incorporation provides for staggered terms for the members of the board of directors and supermajority approval of the removal of any member of the board of directors and prevents our stockholders from acting by written consent. Our certificate also requires supermajority approval of any amendment of these provisions. These provisions and other provisions of our by-laws and of Delaware law applicable to us could delay or make more difficult a merger, tender offer or proxy contest involving us.

We have never paid dividends on our common stock and do not anticipate doing so in the foreseeable future.

We have never paid cash dividends on our stock. We currently intend to retain all future earnings, if any, for use in the operation of our business. Accordingly, we do not anticipate paying cash dividends on our common stock in the foreseeable future.

Item 6. Exhibits

See the Exhibit Index attached to this quarterly report and 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 on this 8th day of November, 2016.

BIOCRYST PHARMACEUTICALS, INC.

/s/ Jon P. Stonehouse
Jon P. Stonehouse
President and Chief Executive Officer

(Principal Executive Officer)

/s/ Thomas R. Staab, II
Thomas R. Staab, II
*Senior Vice President, Chief Financial
Officer and Treasurer*
*(Principal Financial and Principal
Accounting Officer)*

INDEX TO EXHIBITS

Number Description

- 3.1 Third Restated Certificate of Incorporation of Registrant. Incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed December 22, 2006.
- 3.2 Certificate of Amendment to the Third Restated Certificate of Incorporation of Registrant. Incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed July 24, 2007.
- 3.3 Certificate of Increase of Authorized Number of Shares of Series B Junior Participating Preferred Stock. Incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed November 4, 2008.
- 3.4 Certificate of Amendment to the Third Restated Certificate of Incorporation of Registrant. Incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed May 8, 2014.
- 3.5 Certificate of Increase of Authorized Number of Shares of Series B Junior Participating Preferred Stock. Incorporated by reference to Exhibit 3.2 to the Company's Form 8-K filed May 8, 2014.
- 3.6 Amended and Restated Bylaws of Registrant effective October 29, 2008. Incorporated by reference to Exhibit 3.2 to the Company's Form 8-K filed November 4, 2008.
- (10.1)† Amendment #19 to the Agreement between BioCryst Pharmaceuticals, Inc. and the National Institute of Allergy and Infectious Diseases, dated August 10, 2016. (Portions omitted pursuant to request for confidential treatment.)
- (10.2) Amendment #7 to the Agreement between BioCryst Pharmaceuticals, Inc. and the Biomedical Advanced Research and Development Authority within the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response, dated September 26, 2016.
- (10.3)† Credit and Security Agreement, dated as of September 23, 2016, by and among Midcap Financial Trust, as administrative agent, the Lenders listed on the Credit Facility Schedule attached thereto and otherwise party thereto from time to time, BioCryst Pharmaceuticals, Inc., and MDCP, LLC. (Portions omitted pursuant to request for confidential treatment.)
- (31.1) Certification of the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- (31.2) Certification of the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- (32.1) Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- (32.2) Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- (101)

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Financial statements from the Quarterly Report on Form 10-Q of BioCryst Pharmaceuticals, Inc. for the three months ended September 30, 2016, formatted in XBRL: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Comprehensive Loss, (iii) Consolidated Statements of Cash Flows, and (iv) Notes to Consolidated Financial Statements.

() Filed or furnished herewith.

† Confidential treatment requested.