UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2021

OR

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

FOR THE TRANSITION PERIOD FROM TO

Commission File Number 0-29889

Rigel Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**94-3248524**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
1180 Veterans Blvd. South San Francisco, CA (Address of principal executive offices)	**94080** (Zip Code)

(650) 624-1100
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class:	Trading Symbol	Name of each exchange on which registered:
Common Stock, par value $0.001 per share	RIGL	The Nasdaq Stock Market LLC

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

Indicate by check mark whether the registrant has submitted electronically, every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer ☐	Accelerated filer ☒
Non-accelerated filer ☐	Smaller reporting company ☒
Emerging Growth Company ☐	

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

As of October 29, 2021, there were 171,006,061 shares of the registrant's Common Stock outstanding.

RIGEL PHARMACEUTICALS, INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2021

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

RIGEL PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS
(In thousands)

	September 30, 2021 (unaudited)	December 31, 2020(1)
Assets		
Current assets:		
Cash and cash equivalents	$ 30,403	$ 30,373
Short-term investments	112,743	26,954
Accounts receivable, net	14,991	15,973
Inventories	7,035	1,638
Prepaid and other current assets	5,932	14,045
Total current assets	171,104	88,983
Property and equipment, net	2,655	2,676
Operating lease right-of-use asset	11,824	17,895
Other assets	935	824
	$ 186,518	$ 110,378
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,144	$ 3,707
Accrued compensation	9,461	9,592
Accrued research and development	9,475	4,889
Other accrued liabilities	13,486	11,014
Lease liabilities, current portion	9,574	8,621
Deferred revenue	3,157	3,018
Other long-term liabilities, current portion	10,985	—
Total current liabilities	59,282	40,841
Long-term portion of lease liabilities	3,314	10,651
Loans payable, net of discount	19,887	19,815
Other long-term liabilities	54,365	5,045
Commitments		
Stockholders' equity:		
Preferred stock	—	—
Common stock	171	169
Additional paid-in capital	1,350,736	1,339,833
Accumulated other comprehensive income (loss)	8	(4)
Accumulated deficit	(1,301,245)	(1,305,972)
Total stockholders' equity	49,670	34,026
	$ 186,518	$ 110,378

(1) The balance sheet as of December 31, 2020 has been derived from the audited financial statements included in Rigel's Annual Report on Form 10-K for the year ended December 31, 2020 filed with the Securities and Exchange Commission (SEC) on March 2, 2021.

See Accompanying Notes to Condensed Financial Statements

RIGEL PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenues:				
Product sales, net	$ 16,012	$ 16,289	$ 45,441	$ 43,943
Contract revenues from collaborations	4,531	2,100	73,886	46,228
Government contract	1,000	—	9,500	—
Total revenues	21,543	18,389	128,827	90,171
Costs and expenses:				
Cost of product sales	151	140	596	574
Research and development	18,300	14,600	51,933	44,963
Selling, general and administrative	22,877	17,430	67,376	54,780
Total costs and expenses	41,328	32,170	119,905	100,317
Income (loss) from operations	(19,785)	(13,781)	8,922	(10,146)
Interest income	14	36	31	563
Interest expense	(1,317)	(429)	(3,561)	(924)
Income (loss) before income taxes	(21,088)	(14,174)	5,392	(10,507)
Provision for (benefit from) income taxes	(136)	—	665	—
Net income (loss)	$ (20,952)	$ (14,174)	$ 4,727	$ (10,507)
Net income (loss) per share				
Basic	$ (0.12)	$ (0.08)	$ 0.03	$ (0.06)
Diluted	$ (0.12)	$ (0.08)	$ 0.03	$ (0.06)
Weighted average shares used in computing net income (loss) per share				
Basic	170,886	168,932	170,297	168,658
Diluted	170,886	168,932	176,452	168,658

See Accompanying Notes to Condensed Financial Statements

RIGEL PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF COMPREHENSIVE INCOME
(In thousands)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net income (loss)	$ (20,952)	$ (14,174)	$ 4,727	$ (10,507)
Other comprehensive income (loss):				
Net unrealized gain (loss) on short-term investments	1	(44)	12	(21)
Comprehensive income (loss)	$ (20,951)	$ (14,218)	$ 4,739	$ (10,528)

See Accompanying Notes to Condensed Financial Statements

RIGEL PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands, except share amounts)
(unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of January 1, 2021	169,316,782	$ 169	$ 1,339,833	$ (4)	$ (1,305,972)	$ 34,026
Net income	—	—	—	—	39,500	39,500
Net unrealized gain on short-term investments	—	—	—	3	—	3
Issuance of common stock upon exercise of options	813,854	1	2,096	—	—	2,097
Stock-based compensation expense	—	—	2,672	—	—	2,672
Balance as of March 31, 2021	170,130,636	$ 170	$ 1,344,601	$ (1)	$ (1,266,472)	$ 78,298
Net loss	—	—	—	—	(13,821)	(13,821)
Net unrealized gain on short-term investments	—	—	—	8	—	8
Issuance of common stock upon exercise of options and participation in Purchase Plan	711,847	1	1,318	—	—	1,319
Stock-based compensation expense	—	—	2,306	—	—	2,306
Balance as of June 30, 2021	170,842,483	$ 171	$ 1,348,225	$ 7	$ (1,280,293)	$ 68,110
Net loss	—	—	—	—	(20,952)	(20,952)
Net unrealized gain on short-term investments	—	—	—	1	—	1
Issuance of common stock upon exercise of options	127,265	—	274	—	—	274
Stock-based compensation expense	—	—	2,237	—	—	2,237
Balance as of September 30, 2021	170,969,748	$ 171	$ 1,350,736	$ 8	$ (1,301,245)	$ 49,670

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of January 1, 2020	167,987,850	$ 168	$ 1,329,852	$ 23	$ (1,276,228)	$ 53,815
Net income	—	—	—	—	21,243	21,243
Net unrealized gain on short-term investments	—	—	—	55	—	55
Issuance of common stock upon exercise of options	581,675	1	1,335	—	—	1,336
Stock-based compensation expense	—	—	2,050	—	—	2,050
Balance as of March 31, 2020	168,569,525	$ 169	$ 1,333,237	$ 78	$ (1,254,985)	$ 78,499
Net loss	—	—	—	—	(17,576)	(17,576)
Net unrealized loss on short-term investments	—	—	—	(32)	—	(32)
Issuance of common stock upon exercise of options and participation in Purchase Plan	348,098	—	541	—	—	541
Stock-based compensation expense	—	—	1,778	—	—	1,778
Balance as of June 30, 2020	168,917,623	$ 169	$ 1,335,556	$ 46	$ (1,272,561)	$ 63,210
Net loss	—	—	—	—	(14,174)	(14,174)
Net unrealized loss on short-term investments	—	—	—	(44)	—	(44)
Issuance of common stock upon exercise of options	25,811	—	52	—	—	52
Stock-based compensation expense	—	—	1,911	—	—	1,911
Balance as of September 30, 2020	168,943,434	$ 169	$ 1,337,519	$ 2	$ (1,286,735)	$ 50,955

See Accompanying Notes to Condensed Financial Statements

RIGEL PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(In thousands)
(unaudited)

	Nine Months Ended September 30,	
	2021	2020
Operating activities		
Net income (loss)	$ 4,727	$ (10,507)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Stock-based compensation expense	7,147	5,665
Depreciation and amortization	758	500
Non-cash interest expense	2,314	—
Net amortization and accretion of discount on short-term investments and term loan	171	(171)
Changes in assets and liabilities:		
Accounts receivable, net	982	(4,520)
Inventories	(5,325)	(235)
Prepaid and other current assets	8,113	(893)
Other assets	(111)	(124)
Right-of-use assets	6,071	5,836
Accounts payable	(656)	(1,869)
Accrued compensation	(131)	(646)
Accrued research and development	4,586	(2,664)
Other accrued liabilities	2,563	1,731
Lease liability	(6,384)	(5,239)
Deferred revenue	139	(23,477)
Net cash provided by (used in) operating activities	24,964	(36,613)
Investing activities		
Purchases of short-term investments	(117,076)	(63,671)
Maturities of short-term investments	31,200	103,184
Capital expenditures	(648)	(758)
Net cash (used in) provided by investing activities	(86,524)	38,755
Financing activities		
Cost share advance from collaboration partner	57,900	—
Net proceeds from issuances of common stock upon exercise of options and participation in Purchase Plan	3,690	1,929
Net proceeds from term loan financing	—	9,975
Net cash provided by financing activities	61,590	11,904
Net increase in cash and cash equivalents	30	14,046
Cash and cash equivalents at beginning of period	30,373	22,521
Cash and cash equivalents at end of period	$ 30,403	$ 36,567
Supplemental disclosure of cash flow information		
Interest paid	$ 1,094	$ 814

See Accompanying Notes to Condensed Financial Statements

Rigel Pharmaceuticals, Inc.
Notes to Condensed Financial Statements
(unaudited)

In this report, "Rigel," "we," "us" and "our" refer to Rigel Pharmaceuticals, Inc.

1. Nature of Operations

We are a biotechnology company dedicated to discovering, developing and providing novel small molecule drugs that significantly improve the lives of patients with hematologic disorders, cancer and rare immune diseases. Our pioneering research focuses on signaling pathways that are critical to disease mechanisms. Our first product approved by the United States Food and Drug Administration (FDA) is TAVALISSE® (fostamatinib disodium hexahydrate) tablets, the only oral spleen tyrosine kinase (SYK) inhibitor, for the treatment of adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment. The product is also commercially available in Europe, the United Kingdom (TAVLESSE) and Canada (TAVALISSE) for the treatment of chronic ITP in adult patients.

Fostamatinib is currently being studied in a Phase 3 trial for the treatment of warm autoimmune hemolytic anemia (wAIHA); a Phase 3 clinical trial for the treatment of hospitalized high-risk patients with COVID-19; a National Institute of Health (NIH)/National Heart, Lung, and Blood Institute (NHLBI) sponsored Phase 3 trial (ACTIV-4 Host Tissue Trial) for the treatment of COVID-19 in hospitalized patients; and a Phase 2 trial for the treatment of COVID-19 being conducted by Imperial College London.

Our other clinical programs include our interleukin receptor-associated kinase (IRAK) inhibitor program and a receptor-interacting serine/threonine-protein kinase (RIP1) inhibitor program in clinical development with partner Eli Lilly and Company (Lilly). In addition, we have product candidates in clinical development with partners AstraZeneca AB (AZ), BerGenBio ASA (BerGenBio) and Daiichi Sankyo (Daiichi).

2. Basis of Presentation

Our accompanying unaudited condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP), for interim financial information and pursuant to the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities Act of 1933, as amended (Securities Act). Accordingly, they do not include all the information and notes required by U.S. GAAP for complete financial statements. These unaudited condensed financial statements include only normal and recurring adjustments that we believe are necessary to fairly state our financial position and the results of our operations and cash flows. Interim-period results are not necessarily indicative of results of operations or cash flows for a full-year or any subsequent interim period. The balance sheet as of December 31, 2020 has been derived from audited financial statements at that date but does not include all disclosures required by U.S. GAAP for complete financial statements. Because certain disclosures required by U.S. GAAP for complete financial statements are not included herein, these interim unaudited condensed financial statements and the notes accompanying them should be read in conjunction with our audited financial statements and the notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2020.

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results could differ from these estimates.

3. Summary of Significant Accounting Policies

Recently Adopted Accounting Pronouncement

In December 2019, the Financial Accounting Standards Board (FASB) issued ASU No. 2019-12,*Income Taxes (Topic 740) Simplifying the Accounting for Income Taxes*, which simplifies the accounting for income taxes by removing variety of exceptions within the framework of ASC 740. There were nine amendments in the ASU, such as the elimination of the incremental approach to intraperiod tax allocation, recognition of deferred tax liability for outside basis differences, changes to the accounting of hybrid tax regimes, amendments to the accounting of tax basis step-up in goodwill, clarification on separate financial statements of legal entities not subject to tax, guidance on the accounting for ownership changes in investments, and guidance on interim-period accounting for tax law changes and year-to-date loss limitations. The guidance is effective for fiscal years beginning after December 15, 2020 and for interim periods within those fiscal years. We adopted this new guidance effective in the first quarter of 2021 with no material impact on our financial statements and disclosures.

Inventories

Inventories are stated at the lower of cost or estimated net realizable value. We determine the cost of inventories using the standard cost method, which approximates actual cost based on a first-in, first-out basis. Inventories consist primarily of third-party manufacturing costs and allocated internal overhead costs. We began capitalizing inventory costs associated with our product upon regulatory approval when, based on management's judgment, future commercialization was considered probable and the future economic benefit was expected to be realized.

Prior to FDA approval of TAVALISSE, all manufacturing costs were charged to research and development expense in the period incurred. As of September 30, 2021 and December 31, 2020, our physical inventory included active pharmaceutical product for which costs have been previously charged to research and development expense. However, manufacturing of drug product, finished bottling and other labeling activities that occurred post FDA approval are included in the inventory value at each balance sheet date.

We provide reserves for potential excess, dated or obsolete inventories based on an analysis of forecasted demand compared to quantities on hand and any firm purchase orders, as well as product shelf life.

Cost of Product Sales

Cost of product sales consists of third-party manufacturing costs, transportation and freight, and indirect overhead costs associated with the manufacture and distribution of TAVALISSE. A portion of the cost of producing the product sold to date was expensed as research and development prior to the Company's New Drug Application approval for TAVALISSE and therefore is not included in the cost of product sales during this period.

Accounts Receivable

Accounts receivable are recorded net of customer allowances for prompt payment discounts and any allowance for doubtful accounts. We estimate the allowance for doubtful accounts based on existing contractual payment terms, actual payment patterns of our customers and individual customer circumstances. As of September 30, 2021 and December 31, 2020, customer allowance for prompt payment discounts were $100,000 and $171,000, respectively. To date, we have determined that an allowance for doubtful accounts is not required.

Revenue Recognition

We recognize revenue in accordance with ASC Topic 606,*Revenue From Contracts with Customers (ASC 606)*, when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. To determine whether arrangements are within the scope of ASC 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies its performance obligation. We apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the scope of this new guidance, we assess the goods or services promised

within each contract and identify, as a performance obligation, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Product Sales

Revenues from product sales are recognized when the specialty distributors (SDs), who are our customers, obtain control of our product, which occurs at a point in time, upon delivery to such SDs. These SDs subsequently resell our products to specialty pharmacy providers, health care providers, hospitals and clinics. In addition to distribution agreements with these SDs, we also enter into arrangements with specialty pharmacy providers, in-office dispensing providers, group purchasing organizations, and government entities that provide for government-mandated and/or privately-negotiated rebates, chargebacks and discounts with respect to the purchase of our products.

Under ASC 606, we are required to estimate the transaction price, including variable consideration that is subject to a constraint, in our contracts with our customers. Variable consideration is included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur. Revenue from product sales are recorded net of certain variable consideration which includes estimated government-mandated rebates and chargebacks, distribution fees, estimated product returns and other deductions.

Provisions for returns and other adjustments are provided for in the period the related revenue is recorded. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, we will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

The following are our significant categories of sales discounts and allowances:

Sales Discounts. We provide our customers prompt payment discounts that are explicitly stated in our contracts and are recorded as a reduction of revenue in the period the related product revenue is recognized.

Product Returns. We offer our SDs a right to return product purchased directly from us, which is principally based upon the product's expiration date. Product return allowances are estimated and recorded at the time of sale.

Government Rebates: We are subject to discount obligations under the state Medicaid programs and Medicare prescription drug coverage gap program. We estimate our Medicaid and Medicare prescription drug coverage gap rebates based upon a range of possible outcomes that are probability-weighted for the estimated payor mix. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability that is included as part of Other Accrued Liabilities account in the Balance Sheet. Our liability for these rebates consists primarily of estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but remains in the distribution channel inventories at the end of each reporting period.

Chargebacks and Discounts: Chargebacks for fees and discounts represent the estimated obligations resulting from contractual commitments to sell products to certain specialty pharmacy providers, in-office dispensing providers, group purchasing organizations, and government entities at prices lower than the list prices charged to our SDs who directly purchase the product from us. These SDs charge us for the difference between what they pay for the product and our contracted selling price to these specialty pharmacy providers, in-office dispensing providers, group purchasing organizations, and government entities. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue. Actual chargeback amounts are generally determined at the time of resale to the specialty pharmacy providers, in-office dispensing providers, group purchasing organizations, and government entities by our SDs. The estimated obligations arising from these chargebacks and discounts are included as part of Other Accrued Liabilities in the balance sheet.

Co-Payment Assistance: We offer co-payment assistance to commercially insured patients meeting certain eligibility requirements. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that we expect to receive associated with product that has been recognized as revenue.

Contract Revenues from Collaborations

In the normal course of business, we conduct research and development programs independently and in connection with our corporate collaborators, pursuant to which we license certain rights to our intellectual property to third parties. The terms of these arrangements typically include payment to us for a combination of one or more of the following: upfront license fees; development, regulatory and commercial milestone payments; product supply services; and royalties on net sales of licensed products.

Upfront License Fees: If the license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenues from upfront license fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, we determine whether the combined performance obligation is satisfied over time or at a point in time. If the combined performance obligation is satisfied over time, we use judgment in determining the appropriate method of measuring progress for purposes of recognizing revenue from the up-front license fees. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

For arrangements that require us to share in the development costs but to which we do not participate in the co-development work, the portion of the upfront fee attributed to our share in the future development costs is excluded from the transaction price. If such share in the development costs is payable beyond 12 months from the delivery of the corresponding license, a significant financing component is deemed to exist. If a significant financing component is identified, we adjust the transaction price by reducing the upfront fee by the net present value of our share in future development costs over the expected commitment period. Such discounted amount will be reported as a liability in the balance sheet, with a corresponding interest expense being accreted based on a discount rate applied over the expected commitment period.

Development, Regulatory or Commercial Milestone Payments: At the inception of each arrangement that includes payments based on the achievement of certain development, regulatory and commercial or launch events, we evaluate whether the milestones are considered probable of being achieved and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until uncertainty associated with the approvals has been resolved. The transaction price is then allocated to each performance obligation, on a relative standalone selling price basis, for which we recognize revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, we re-evaluate the probability of achieving such development and regulatory milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, and recorded as part of contract revenues from collaborations during the period of adjustment.

Product Supply Services: Arrangements that include a promise for future supply of drug product for either clinical development or commercial supply at the licensee's discretion are generally considered as options. We assess if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations.

Sales-based Milestone Payments and Royalties: For arrangements that include sales-based royalties, including milestone payments based on the volume of sales, we determine whether the license is deemed to be the predominant item to which the royalties or sales-based milestones relate to and if such is the case, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Government Contract

As described in Note 8 below, in January 2021, we were awarded up to $16.5 million by the U.S. Department of Defense's Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (referred here as U.S. Department of Defense) to support our ongoing Phase 3 clinical trial to evaluate the safety and efficacy of fostamatinib for the treatment of hospitalized high-risk patients with COVID-19. We determined that the government award should be accounted for under IAS 20, *Accounting for Government Grants and Disclosure of Government Assistance,* which is outside the scope of Topic 606, as the U.S. Department of Defense is not receiving reciprocal value for their contributions. Revenue is recognized when there is reasonable assurance that the conditions of the grant will be met, and the grant will be received. For the U.S. Department of Defense's contract, this occurs when either each milestone has been accepted by Department of Defense or management has concluded that the conditions of the grant have been substantially met.

Leases

We currently lease our research and office space under a noncancelable lease agreement with our landlord through January 2023. In December 2014, we entered into a sublease agreement with an unrelated third party to occupy a portion of our research and office space through January 2023.

All of our leases outstanding as September 30, 2021 continued to be classified as operating leases. We recorded an operating lease right-of-use asset and an operating lease liability on our balance sheet. Right-of-use lease assets represent our right to use the underlying asset for the lease term and the lease obligation represents our commitment to make the lease payments arising from the lease. Right-of-use lease assets and obligations are recognized at the commencement date based on the present value of remaining lease payments over the lease term. As our lease does not provide an implicit rate, we have used an estimated incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. The operating lease right-of-use asset includes any lease payments made prior to commencement. The lease term may include options to extend or terminate the lease when it is reasonably certain that we will exercise that option. Operating lease expense is recognized on a straight-line basis over the lease term, subject to any changes in the lease or expectations regarding the terms. Variable lease costs such as common area costs and property taxes are expensed as incurred. Leases with an initial term of 12 months or less are not recorded on the balance sheet.

For our sublease agreement wherein we are the lessor, sublease income will be recognized on a straight-line basis over the term of the sublease. The difference between the cash received, and the straight-line lease income recognized, if any, will be recorded as part of prepaid and other current assets in the balance sheet.

Research and Development Accruals

We have various contracts with third parties related to our research and development activities. Costs that are incurred but not billed to us as of the end of the period are accrued. We make estimates of the amounts incurred in each period based on the information available to us and our knowledge of the nature of the contractual activities generating such costs. Clinical trial contract expenses are accrued based on units of activity. Expenses related to other research and development contracts, such as research contracts, toxicology study contracts and manufacturing contracts are estimated to be incurred generally on a straight-line basis over the duration of the contracts. Raw materials and study materials not related to our approved drug, purchased for us by third parties are expensed at the time of purchase.

Income Taxes

Income taxes have been provided using the liability method whereby deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities and net operating loss and tax credit carryforwards measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse or the carryforwards are utilized. Valuation allowances are established when it is determined that it is more likely than not that such assets will not be realized.

We account for uncertain tax positions consistent with authoritative guidance. The guidance prescribes a "more likely than not" recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. We do not expect any material change in our unrecognized tax benefits over the next 12 months. We recognize interest and penalties related to unrecognized tax

benefits as a component of income taxes.

4. Net Income (Loss) Per Share

Basic net income (loss) per share is computed by dividing net income (loss) by the weighted-average number of shares of common stock outstanding during the period. Diluted net income (loss) per share is computed by dividing net income (loss) by the weighted-average number of shares of common stock outstanding during the period and the number of additional shares of common stock that would have been outstanding if potentially dilutive securities had been issued. Potentially dilutive securities include stock options, restricted stock units and shares issuable under our Purchase Plan. The dilutive effect of these potentially dilutive securities is reflected in diluted earnings per share by application of the treasury stock method. Under the treasury stock method, an increase in the fair market value of our common stock can result in a greater dilutive effect from potentially dilutive securities.

The following table sets forth the computation of basic and diluted earnings per share (in thousands except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
EPS Numerator:				
Net income (loss)	$ (20,952)	$ (14,174)	$ 4,727	$ (10,507)
EPS Denominator—Basic:				
Weighted-average common shares outstanding	170,886	168,932	170,297	168,658
EPS Denominator—Diluted:				
Weighted-average common shares outstanding	170,886	168,932	170,297	168,658
Dilutive effect of stock options, restricted stock units and shares under Purchase Plan	—	—	6,155	—
Weighted-average shares outstanding and common stock equivalents	170,886	168,932	176,452	168,658
Net income (loss) per share				
Basic	$ (0.12)	$ (0.08)	$ 0.03	$ (0.06)
Diluted	$ (0.12)	$ (0.08)	$ 0.03	$ (0.06)

The potential shares of common stock that were excluded from the computation of diluted net income (loss) per share for the periods presented because including them would have been antidilutive are as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Outstanding stock options	30,490	27,646	9,450	27,646
Restricted stock units	234	—	4	—
Purchase Plan	313	59	—	59
Total	31,037	27,705	9,454	27,705

5. Stock Award Plans

On May 16, 2018, our stockholders approved the adoption of the Company's 2018 Equity Incentive Plan (2018 Plan). The 2018 Plan is the successor plan to the 2011 Equity Incentive Plan, the 2000 Equity Incentive Plan, and the 2000 Non-Employee Directors' Stock Option Plan.

We have two equity plans, our 2018 Plan and the Company's Inducement Plan, as amended (collectively, the Equity Incentive Plans), that provide for granting of stock awards to our officers, directors and all other employees and consultants. To date, we granted stock options and restricted stock units under our Equity Incentive Plans. We also have our Employee Stock Purchase Plan (Purchase Plan), wherein eligible employees can purchase shares of our common stock at a price per share equal to the lesser of 85% of the fair market value on the first day of the offering period or 85% of the fair market value on the purchase date. The fair value of each option award is estimated on the date of grant using

the Black-Scholes option pricing model which considered our stock price, as well as assumptions regarding a number of complex and subjective variables. The fair value of the restricted stock unit grant is based on the market price of our common stock on the date of grant. We use the straight-line attribution method over the requisite employee service period for the entire award in recognizing stock-based compensation expense. We account for forfeitures as they occur.

We granted performance-based stock options to purchase shares of our common stock which will vest upon the achievement of certain corporate performance-based milestones. We determined the fair values of these performance-based stock options using the Black-Scholes option pricing model at the date of grant. For the portion of the performance-based stock options of which the performance condition is considered probable of achievement, we recognize stock-based compensation expense on the related estimated grant date fair values of such options on a straight-line basis from the date of grant up to the date when we expect the performance condition will be achieved. For the performance conditions that are not considered probable of achievement at the grant date or upon quarterly re-evaluation, prior to the event actually occurring, we recognize the related stock-based compensation expense when the event occurs or when we can determine that the performance condition is probable of achievement. In those cases, we recognize the change in estimate at the time we determine the condition is probable of achievement (by recognizing stock-based compensation expense as cumulative catch-up adjustment as if we had estimated at the grant date that the performance condition would have been achieved) and recognize the remaining compensation cost up to the date when we expect the performance condition will be achieved, if any.

6. Stock-Based Compensation

Total stock-based compensation related to all of our share-based payments that we recognized for the three and nine months ended September 30, 2021 and 2020 were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Selling, general and administrative	$ 1,800	$ 1,352	$ 5,625	$ 3,981
Research and development	402	532	1,522	1,684
Total stock-based compensation expense	$ 2,202	$ 1,884	$ 7,147	$ 5,665

During the nine months ended September 30, 2021, we granted options to purchase6,373,981 shares of common stock with a grant-date weighted-average fair value of $2.36 per share, and 1,176,386 options to purchase shares were exercised.As of September 30, 2021, total stock options outstanding was 30,489,827 shares, of which, 2,018,125 shares outstanding are performance-based stock options wherein the achievement of the corresponding corporate-based milestones was not considered as probable. Accordingly, the related grant date fair value for these performance-based stock options of $4.2 million has not been recognized as stock-based compensation expense as of September 30, 2021. The exercise price of stock options granted under our stock plans is equal to the fair market value of the underlying shares on the date of grant. Options become exercisable at varying dates and generally expire 10 years from the date of grant.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model. We have segregated option awards into the following three homogenous groups for the purposes of determining fair values of options: officers and directors, all other employees, and consultants. We account for forfeitures as they occur.

We determined weighted-average valuation assumptions separately for each of these groups as follows:

- Volatility—We estimated volatility using our historical share price performance over the expected life of the option. We also considered other factors, such as implied volatility, our current clinical trials and other company activities that may affect the volatility of our stock in the future. We determined that at this time historical volatility is more indicative of our expected future stock performance than implied volatility.
- Expected term—For options granted to consultants, we use the contractual term of the option, which is generallyten years, for the initial valuation of the option and the remaining contractual term of the option for the succeeding periods. We analyzed various historical data to determine the applicable

expected term for each of the other option groups. This data included: (1) for exercised options, the term of the options from option grant date to exercise date; (2) for cancelled options, the term of the options from option grant date to cancellation date, excluding non-vested option forfeitures; and (3) for options that remained outstanding at the balance sheet date, the term of the options from option grant date to the end of the reporting period and the estimated remaining term of the options. The consideration and calculation of the above data gave us reasonable estimates of the expected term for each employee group. We also considered the vesting schedules of the options granted and factors surrounding exercise behavior of the option groups, our current market price and company activity that may affect our market price. In addition, we considered the optionee type (i.e., officers and directors or all other employees) and other factors that may affect the expected term of the options.

- Risk-free interest rate—The risk-free interest rate is based on U.S. Treasury constant maturity rates with similar terms to the expected term of the options for each option group.
- Dividend yield—The expected dividend yield is0% as we have not paid and do not expect to pay dividends in the future.

The following table summarizes the weighted-average assumptions relating to options granted pursuant to our Equity Incentive Plans for the three and nine months ended September 30, 2021 and 2020:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Risk-free interest rate	1.1 %	0.5 %	1.0 %	1.2 %
Expected term (in years)	6.0	6.7	6.5	6.5
Dividend yield	0.0 %	0.0 %	0.0 %	0.0 %
Expected volatility	70.4 %	70.5 %	70.6 %	66.0 %

During the nine months ended September 30, 2021, we granted233,750 restricted stock units with grant-date weighted-average fair value of $3.67 per share. The restricted stock units granted vests over1 to 2 years, all of which are outstanding as of September 30, 2021.

As of September 30, 2021, there were approximately$15.5 million of unrecognized stock-based compensation cost which is expected to be recognized over the remaining weighted-average period of 1.98 years, related to time-based stock options, RSUs and performance-based stock options, wherein achievement of the corresponding corporate-based milestones was considered as probable.

In January 2021, our Board of Directors approved the825,000 shares increase in available number of shares for future grant under our 2018 Plan, which became effective upon approval by our stockholders during the stockholders annual meeting in May 2021. As of September 30, 2021, there were 10,403,690 shares of common stock available for future grant under our Equity Incentive Plans.

Employee Stock Purchase Plan

Our Purchase Plan permits eligible employees to purchase common stock at a discount through payroll deductions during defined offering periods. The price at which the stock is purchased is equal to the lesser of 85% of the fair market value of our common stock on the first day of the offering or 85% of the fair market value of our common stock on the purchase date.

The fair value of awards granted under our Purchase Plan is estimated on the date of grantusing the Black-Scholes option pricing model, which uses weighted-average assumptions. Our Purchase Plan provides for atwenty-four-month offering period comprised of four six-month purchase periods with a look-back option. A look-back option is a provision in our Purchase Plan under which eligible employees can purchase shares of our common stock at a price per share equal to the lesser of 85% of the fair market value on the first day of the offering period or 85% of the fair market value on the purchase date.Our Purchase Plan also includes a feature that provides for a new offering period to begin when the fair market value of our common stock on any purchase date during an offering period falls below the fair

market value of our common stock on the first day of such offering period. This feature is called a "reset." Participants are automatically enrolled in the new offering period.

We had a "reset" in January 2020 because the fair market value of our stock on December 31, 2019 was lower than the fair market value of our stock on January 1, 2019, the first day of the offering period. Following the "reset" in January 2020, January 1, 2020 was the new first day of the two-year offering period of our Purchase Plan. We applied modification accounting in accordance with the relevant accounting guidance. The total incremental fair value associated with this "reset" was approximately $753,000 and is being recognized as expense from January 1, 2020 to December 31, 2021. In July 2020, we had another "reset" because the fair market value of our stock on June 30, 2020 was lower than the fair market value of our stock on January 1, 2020. Following the "reset" in July 2020, July 1, 2020 is the new start date of our two-year offering period of our Purchase Plan. We applied modification accounting in accordance with the relevant accounting guidance. The total incremental fair value associated with this "reset" was approximately $535,000 and is being amortized to expenses from July 1, 2020 to June 30, 2022.

In January 2021, our Board of Directors approved the5,500,000 shares increase in the maximum number of shares authorized for issuance under the Purchase Plan, which became effective upon approval by our stockholders during the annual stockholders meeting in May 2021. As of September 30, 2021, there were5,039,922 shares reserved for future issuance under the Purchase Plan. As of September 30, 2021, unrecognized stock-based compensation cost related to our Purchase Plan amounted to $193,000, which is expected to be recognized over the remaining weighted average period of 0.33 years.

7. Revenues

Revenues disaggregated by category were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Product sales:				
Gross product sales	$ 20,546	$ 20,318	$ 58,692	$ 54,042
Discounts and allowances	(4,534)	(4,029)	(13,251)	(10,099)
Total product sales, net	16,012	16,289	45,441	43,943
Revenues from collaborations:				
License revenues	2,431	—	70,354	39,858
Development milestones	1,875	2,100	1,875	2,100
Research and development services and others	225	—	1,657	4,270
Total revenues from collaborations	4,531	2,100	73,886	46,228
Government contract	1,000	—	9,500	—
Total revenues	$ 21,543	$ 18,389	$ 128,827	$ 90,171

The following table summarizes the percentages of revenues from each of our customers who individually accounted for 10% or more (wherein * denotes less than 10%) of the total net product sales and revenues from collaborations:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
ASD Healthcare and Oncology Supply	25%	48%	15%	26%
McKesson Specialty Care Distribution Corporation	35%	34%	17%	20%
Lilly	12%	—	56%	—
Cardinal Healthcare	18%	*	*	*
Grifols	*	*	*	49%
Daiichi	*	11%	*	*

Our first and only FDA approved product, TAVALISSE®, was approved by the U.S. FDA in April 2018. We commenced commercial sale of TAVALISSE in the U.S. in May 2018. Fostamatinib is marketed in Europe under the

brand name TAVLESSE™ (fostamatinib). In July 2020, Grifols S.A. (Grifols) launched TAVLESSE in the United Kingdom (UK) and Germany. In September 2021, Grifols announced that it began commercializing TAVLESSE in France, Italy and Spain. In December 2020, the Scottish Medicines Consortium accepted TAVLESSE for use in NHS in Scotland.

In addition to the distribution agreements with our customers and SDs, we also enter into arrangements with specialty pharmacy providers, in-office dispensing providers, group purchasing organizations, and government entities that provide for government-mandated and/or privately-negotiated rebates, chargebacks and discounts with respect to the purchase of our products which reduced our gross product sales. Also refer to Revenue Recognition policy discussion in Note 3 above.

The following table summarizes activity in each of the product revenue allowance and reserve categories for the nine months ended September 30, 2021 and 2020 (in thousands):

	Chargebacks, Discounts and Fees	Government and Other Rebates	Returns	Total
Balance at January 1, 2021	$ 2,461	$ 2,115	$ 1,489	$ 6,065
Provision related to current period sales	7,326	3,995	739	12,060
Credit or payments made during the period	(7,073)	(3,367)	(387)	(10,827)
Balance at September 30, 2021	$ 2,714	$ 2,743	$ 1,841	$ 7,298

	Chargebacks, Discounts and Fees	Government and Other Rebates	Returns	Total
Balance at January 1, 2020	$ 1,293	$ 1,801	$ 238	$ 3,332
Provision related to current period sales	5,625	2,775	676	9,076
Adjustment related to prior period sales	(75)	(490)	565	—
Credit or payments made during the period	(5,020)	(2,407)	(72)	(7,499)
Balance at September 30, 2020	$ 1,823	$ 1,679	$ 1,407	$ 4,909

Of the $13.3 million discounts and allowances from gross product sales for the nine months ended September 30, 2021, $12.1 million was accounted for as additions to other accrued liabilities and $1.2 million as reductions in accounts receivable and prepaid and other current assets in the balance sheet. Other accrued liabilities related to the discounts and allowances had a remaining outstanding balance of $7.3 million as of September 30, 2021.

Of the $10.1 million discounts and allowances from gross product sales for the nine months ended September 30, 2020, $9.1 million was accounted for as additions to other accrued liabilities and $1.0 million as reductions in accounts receivable and prepaid and other current assets in the balance sheet. Other accrued liabilities related to the discounts and allowances had a remaining outstanding balance of $4.9 million as of September 30, 2020.

8. Sponsored Research and License Agreements and Government Contract

Sponsored Research and License Agreements

We conduct research and development programs independently and in connection with our corporate collaborators. As of September 30, 2021, we are a party to collaboration agreements with Lilly to develop and commercialize R552, a RIP1 inhibitor, for the treatment of non-central nervous system (non-CNS) diseases and collaboration aimed at developing additional RIP1 inhibitors for the treatment of central nervous system (CNS) diseases; with Grifols to commercialize fostamatinib for human diseases in all indications, including chronic ITP and autoimmune hemolytic anemia (AIHA), in Europe and Turkey; with Kissei Pharmaceutical Co., Ltd. (Kissei) to develop and commercialize fostamatinib in Japan, China, Taiwan and the Republic of Korea; and with Medison Pharma Trading AG

(Medison Canada) and Medison Pharma Ltd. (Medison Israel and, together with Medison Canada, Medison) to commercialize fostamatinib in all indications, including chronic ITP and AIHA, in Canada and Israel, respectively.

Further, we are also a party to collaboration agreements, but do not have ongoing performance obligations, with AZ for the development and commercialization of R256, an inhaled JAK inhibitor; with BerGenBio for the development and commercialization of AXL inhibitors in oncology; and with Daiichi to pursue research related to MDM2 inhibitors, a novel class of drug targets called ligases. Our collaboration agreement with Aclaris related to the development and commercialization of JAK inhibitors for the treatment of alopecia areata and other dermatological conditions was terminated in April 2021.

Under the above existing agreements that we entered into in the ordinary course of business, we received or may be entitled to receive upfront cash payments, payments contingent upon specified events achieved by such partners and royalties on any net sales of products sold by such partners under the agreements. Total future contingent payments to us under all of these agreements could exceed $1.4 billion if all potential product candidates achieved all of the payment triggering events under all of our current agreements (based on a single product candidate under each agreement). Of this amount, $309.5 million relates to the achievement of development events, $303.1 million relates to the achievement of regulatory events and $816.0 million relates to the achievement of certain commercial or launch events. This estimated future contingent amount does not include any estimated royalties that could be due to us if the partners successfully commercialize any of the licensed products. Future events that may trigger payments to us under the agreements are based solely on our partners' future efforts and achievements of specified development, regulatory and/or commercial events.

Global Exclusive License Agreement with Eli Lilly

On February 18, 2021, we entered into a global exclusive license agreement and strategic collaboration with Lilly (Lilly Agreement), which became effective on March 27, 2021, to develop and commercialize R552, a RIP1 inhibitor, for the treatment of non-CNS diseases. In addition, the collaboration is aimed at developing additional RIP1 inhibitors for the treatment of CNS diseases. Pursuant to the terms of the license agreement, we granted to Lilly exclusive rights to develop and commercialize R552 and related RIP1 inhibitors in all indications worldwide. The agreement became effective in March 2021 upon clearance under the Hart-Scott-Rodino (HSR) Antitrust Improvements Act of 1976. The parties' collaboration is governed through a joint governance committee and appropriate subcommittees.

We are responsible for 20% of development costs for R552 in the U.S., Europe, and Japan, up to a specified cap. Lilly is responsible for funding the remainder of all development activities for R552 and other non-CNS disease development candidates. We have the right to opt- out of co-funding the R552 development activities in the U.S., Europe and Japan at two different specified times. If we exercise our first opt- out right (no later than September 30, 2023), under the Lilly Agreement, we are required to fund our share of the R552 development activities in the U.S., Europe, and Japan up to a maximum funding commitment of $65.0 million through April 1, 2024. If we decide not to exercise our opt- out rights, we will be required to share in global development costs of up to certain amounts at a specified cap, as provided for in the Lilly Agreement.

We are responsible for performing and funding initial discovery and identification of CNS disease development candidates. Following candidate selection, Lilly will be responsible for performing and funding all future development and commercialization of the CNS disease development candidates.

Under the terms of the license agreement, we were entitled to receive a non-refundable and non-creditable upfront cash payment amounting to $125.0 million, which we received in April 2021, and a potential for an additional $830.0 million in milestone payments upon the achievement of specified development and regulatory milestones by non-CNS disease products and $255.0 million in milestone payments upon the achievement of specified development and regulatory milestones by CNS disease products. We are also eligible to receive up to $100.0 million in sales milestone payments on a product-by-product basis for non-CNS disease products and up to $150.0 million in sales milestone payments on a product-by-product basis for CNS disease products. In addition, depending on the extent of our co-funding of R552 development activities, we would be entitled to receive tiered royalty payments on net sales of non-CNS disease products at percentages ranging from the mid-single digits to high-teens, subject to certain standard reductions and offsets. We would be entitled to receive tiered royalty payments on net sales of CNS disease products up to low-double digits, subject to certain standard reductions and offsets.

We accounted for this agreement under ASC 606 and identified the following distinct performance obligations at inception of the agreement: (a) granting of the license rights over the non-CNS penetrant intellectual property (IP), and (b) granting of the license rights over the CNS penetrant IP which will be delivered to Lilly upon completion of the additional research and development efforts specified in the agreement. We concluded each of these performance obligations is distinct. We based our assessment on the assumption that Lilly can benefit from each of the licenses on its own by developing and commercializing the underlying product using its own resources.

Under the Lilly Agreement, we are required to share20% of the development costs for R552 in the U.S., Europe and Japan up to a specified cap. Given our rights to opt- out from the development of R552, we believe at the minimum, we have a commitment to fund the development costs up to $65.0 million as discussed above. We considered this commitment to fund the development costs as a significant financing component of the contract, which we accounted for as a reduction of the upfront fee to derive the transaction price. This financing component was recorded as a liability at its net present value of approximately $57.9 million using a 6.4% discount rate. Interest expense is being accreted on such liability over the expected commitment period. Interest expense accreted during the three and nine months ended September 30, 2021 was $836,000 and $1.9 million, respectively. As of September 30, 2021, the outstanding financing liability of $59.8 million to Lilly was included within other long-term liabilities, current portion, and other long-term liabilities in the condensed balance sheet.

We allocated the net transaction price of $67.1 million to each performance obligation based on our best estimate of its relative standalone selling price using the adjusted market assessment approach. We concluded that the license rights over the non-CNS penetrant IP represents functional IP that is not expected to change over time, and we have no ongoing or undelivered obligations relative to such IP that Lilly will benefit from the use of such IP on the delivery date. As such, the transaction price allocated to the non-CNS penetrant IP of $60.4 million was recognized as revenue in the first quarter of 2021 upon delivery of the non-CNS penetrant IP to Lilly in March 2021. For the delivery of license rights over the CNS penetrant IP, we are obligated to perform additional research and development efforts before Lilly can accept the license. The allocated transaction price to the CNS penetrant IP of $6.7 million is being recognized as revenue from the effective date of the Lilly Agreement through the eventual acceptance by Lilly using the input method. We recognized revenue during the three and nine months ended September 30, 2021 of $2.4 million and $6.0 million, respectively, relative to the delivery of CNS penetrant IP. As of September 30, 2021, the remaining deferred revenue amounted to $744,000.

The remaining future variable consideration related to future milestone payments as discussed above were fully constrained because we cannot conclude that it is probable that a significant reversal of the amount of cumulative revenue recognized will not occur, given the inherent uncertainty of success with these future milestones. For sales-based milestones and royalties, we determined that the license is the predominant item to which the royalties or sales-based milestones relate. Accordingly, we will recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). We will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

Grifols License Agreement

In January 2019, we entered into an exclusive license agreement with Grifols to commercialize fostamatinib in all indications, including chronic ITP and AIHA, in Europe and Turkey. Under the agreement, we received an upfront payment of $30.0 million, with the potential for $297.5 million in total regulatory and commercial milestones. We will also receive stepped double-digit royalty payments based on tiered net sales which may reach 30% of net sales. In return, Grifols received exclusive rights to commercialize fostamatinib for human diseases, including chronic ITP, AIHA, and IgAN, in Europe and Turkey. Grifols also received an exclusive option to expand the territory under its exclusive and non-exclusive licenses to include the Middle East, North Africa and Russia (including Commonwealth of Independent States). In November 2020, Grifols exercised its option to include these territories as part of the licensed territories under the agreement. The agreement also required us to continue to conduct our long-term open-label extension study on patients with ITP through European Medicines Agency (EMA) approval of ITP in Europe or until the study ends as well as conduct the Phase 3 trial in AIHA.

In December 2019, we entered into a Drug Product Purchase Agreement with Grifols wherein we agreed to supply and sell to Grifols at 30% mark up the drug product requested under an anticipated first and only purchase order until Grifols enters into a supply agreement directly with a third-party drug product manufacturer. In October 2020, we entered into a Commercial Supply Agreement with Grifols.

In January 2020, the European Commission granted a centralized Marketing Authorization (MA) for fostamatinib valid throughout the European Union and in the UK after the departure of the UK from the European Union for the treatment of chronic immune thrombocytopenia in adult patients who are refractory to other treatments. With this approval, we received in February 2020 a $20.0 million non-refundable payment, comprised of a $17.5 million payment due upon Marketing Authorization Application (MAA) approval by the EMA of fostamatinib for the first indication and a $2.5 million creditable advance royalty payment, based on the terms of our collaboration agreement with Grifols. The above milestone payment was allocated to the distinct performance obligations in the collaboration agreement with Grifols.

We accounted for this agreement under ASC 606 and identified the following distinct performance obligations at inception of the agreement: (a) granting of the license, (b) performance of research and regulatory services related to our ongoing long-term open-label extension study on patients with ITP, and (c) performance of research services related to our Phase 3 study in AIHA. In October 2020, we entered into a commercial supply agreement for the licensed territories. We concluded each of these performance obligations is distinct. We based our assessment on the following: (i) our assessment that Grifols can benefit from the license on its own by developing and commercializing the underlying product using its own resources, and (ii) the fact that the manufacturing services are not highly specialized in nature and can be performed by other vendors. Upon execution of our agreement with Grifols, we determined that the upfront fee of $5.0 million, which is the non-refundable portion of the $30.0 million upfront fee, represented the transaction price. In the first quarter of 2020, we revised the transaction price to include the $25.0 million of the upfront payment that is no longer refundable under our agreement and the $20.0 million payment received that is no longer constrained. We allocated the updated transaction price to the distinct performance obligations in our collaboration agreement based on our best estimate of the relative standalone selling price as follows: (a) for the license, we estimated the standalone selling price using the adjusted market assessment approach to estimate its standalone selling price in the licensed territories; (b) for the research and regulatory services, we estimated the standalone selling price using the cost plus expected margin approach. As a result of the adjusted transaction price, adjustments are recorded on a cumulative catch-up basis, and recorded as part of contract revenues from collaborations in the first quarter of 2020.

The remaining future variable consideration of $277.5 million related to future regulatory and commercial milestones were fully constrained because we cannot conclude that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur, given the inherent uncertainty of success with these future milestones. We are recognizing revenues related the research and regulatory services throughout the term of the respective clinical programs using the input method. For sales-based milestones and royalties, we determined that the license is the predominant item to which the royalties or sales-based milestones relate. Accordingly, we will recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). We will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

As of September 30, 2021 and December 31, 2020, the remaining deferred revenue was $1.0 million and $1.6 million, respectively, related to the performance of research services. During the three and nine months ended September 30, 2021, we recognized $225,000 and $605,000, respectively, in revenue related to the research and development services. During the nine months ended September 30, 2021, we also recognized $1.0 million in revenue for the delivery of drug supplies in the first quarter of 2021 to Grifols for its commercialization.

During the three months ended September 30, 2020, we recognizedno revenues from Grifols. During the nine months ended September 30, 2020, we recognized $39.9 million in revenues in the first quarter of 2020 related to the licensed rights in intellectual property and $3.6 million in revenues in the first and second quarters of 2020 related to the research services performed. During the nine months ended September 30, 2020, we also recognized $651,000 in revenue for delivery of drug supplies in the second quarter of 2020 to Grifols for commercialization.

Kissei License Agreement

In October 2018, we entered into an exclusive license and supply agreement with Kissei to develop and commercialize fostamatinib in all current and potential indications in Japan, China, Taiwan and the Republic of Korea. Kissei is responsible for performing and funding all development activities for fostamatinib in the above-mentioned territories. We received an upfront cash payment of $33.0 million, with the potential for up to an additional $147.0 million in development, regulatory and commercial milestone payments, and will receive mid- to upper twenty percent, tiered, escalated net sales-based payments for the supply of fostamatinib. Under the agreement, we granted Kissei the license rights to fostamatinib in the territories above and are obligated to supply Kissei with drug product for use in clinical trials and pre-commercialization activities. We are also responsible for the manufacture and supply of fostamatinib for all future development and commercialization activities under the agreement.

We accounted for this agreement under ASC 606 and identified the following distinct performance obligations at inception of the agreement: (a) granting of the license, (b) supply of fostamatinib for clinical use and (c) material right associated with discounted fostamatinib that are supplied for use other than clinical or commercial. In addition, we will provide commercial product supply if the product is approved in the licensed territory. We concluded that each of these performance obligations is distinct. We based our assessment on the following: (i) our assessment that Kissei can benefit from the license on its own by developing and commercializing the underlying product using its own resources and (ii) the fact that the manufacturing services are not highly specialized in nature and can be performed by other vendors. Moreover, we determined that the upfront fee of $33.0 million represented the transaction price and was allocated to the performance obligations based on our best estimate of the relative standalone selling price as follows: (a) for the license, we estimated the standalone selling price using the adjusted market assessment approach to estimate its standalone selling price in the licensed territories; (b) for the supply of fostamatinib and the material right associated with discounted fostamatinib, we estimated the standalone selling price using the cost plus expected margin approach. Variable consideration of $147.0 million related to future development and regulatory milestones was fully constrained because we cannot conclude that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur, given the inherent uncertainty of success with these future milestones. We will recognize revenues related to the supply of fostamatinib and material right upon delivery of fostamatinib to Kissei. For sales-based milestones and royalties, we determined that the license is the predominant item to which the royalties or sales-based milestones relate to. Accordingly, we will recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). We will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

We did not recognize any revenue with regards to the performance obligations related to the supply of fostamatinib and material right associated with discounted fostamatinib supply during the three and nine months ended September 30, 2021 and 2020. As of September 30, 2021 and December 31, 2020, the remaining deferred revenue was $1.4 million.

Medison Commercial and License Agreements

In October 2019, we entered into two exclusive commercial and license agreements with Medison for the commercialization of fostamatinib for chronic ITP in Israel and in Canada, pursuant to which we received a $5.0 million

upfront payment with respect to the agreement in Canada. We accounted for the agreement made with an upfront payment under ASC 606 and identified the following combined performance obligations at inception of the agreement: (a) granting of the license and (b) obtaining regulatory approval in Canada of fostamatinib in ITP. We determined that the non-refundable upfront fee of $5.0 million represented the transaction price. However, under the agreement, we have the option to buy back all rights to the product in Canada within six months from obtaining regulatory approval for the treatment of AIHA in Canada. The buyback option precludes us from transferring control of the license to Medison under ASC 606. We believe that the buyback provision, if exercised, will require us to repurchase the license at an amount equal to or more than the upfront $5.0 million. As such, this arrangement was accounted for as a financing arrangement. During the three and nine months ended September 30, 2021, we accrued interest amounting to $50,000 and $387,000, respectively, related to this financing arrangement. No interest was accrued during the three and nine months ended September 30, 2020. Pursuant to this exclusive commercialization license agreement, in August 2020, we entered into a commercial supply agreement with Medison. As of September 30, 2021, the outstanding financing liability of $5.5 million to Medison was included within other long-term liabilities in the condensed balance sheet.

In August 2021, Medison Israel received the licenses for registrational approval from the Ministry of Health. Pursuant to the exclusive commercial and license agreement, this event triggered the first milestone that is the regulatory approval of the product in Israel for the first indication, for a non-refundable payment of $75,000. We recognized this amount as revenue during the three and nine months ended September 30, 2021.

Daiichi Collaboration Agreement

Pursuant to the Amended Collaboration Agreement dated April 20, 2005 with Daiichi, during the three and nine months ended September 30, 2021, we recognized $1.8 million of revenue related to the achievement of a certain milestone, of which the payment was received in October 2021. During the three and nine months ended September 2020, we also recognized $2.1 million related to the achievement of a certain milestone, of which payment was received in October 2020. All deliverables under the agreement had been previously delivered, and as such the above had been recognized as revenue in the corresponding periods such milestones were achieved.

Other license agreements

In February 2021, we entered into a non-exclusive license agreement with an unrelated third party whereby we granted such unrelated third-party rights to a certain patent. In consideration for the license rights granted, we received a one-time fee of $4.0 million. All the deliverables under the agreement had been delivered and the one-time fee was recognized as revenue in the first quarter of 2021.

Government Contract - U.S. Department of Defense's JPEO-CBRND

In January 2021, we were awarded up to $16.5 million by the U.S. Department of Defense to support our ongoing Phase 3 clinical trial to evaluate the safety and efficacy of fostamatinib for the treatment of hospitalized high-risk patients with COVID-19. The amount of award we will receive from the U.S. Department of Defense is subject to submission of proper documentation as evidence of completion of certain clinical trial events or milestones as specified in the agreement, and approval by the U.S. Department of Defense that such events or milestones have been met. We determined that this government award should be accounted for under IAS 2, *Accounting for Government Grants and Disclosure of Government Assistance,* which is outside of the scope of Topic 606, as the U.S. Department of Defense is not receiving reciprocal value for their contributions. We record government contract revenue in the statement of operations in the period when it is probable that we will receive the award, which is when we comply with the conditions associated with the award and obtain approval from the U.S. Department of Defense that such conditions have been met. For the three and nine months ended September 30, 2021, we recognized $1.0 million and $9.5 million, respectively, related to this grant, all of which had been invoiced and collected as of September 30, 2021. We expect to receive the remaining award of $7.0 million throughout the period we conduct our clinical trial, subject to us meeting certain clinical trial events or milestones and approval by the U.S. Department of Defense as specified in the agreement.

9. Inventories

As of September 30, 2021 and December 31, 2020, we have the following inventories (in thousands):

	September 30, 2021	December 31, 2020
Raw materials	$ 5,142	$ —
Work in process	483	1,189
Finished goods	1,410	449
Total	$ 7,035	$ 1,638

As of December 31, 2020, we have $4.0 million in advance payments to our manufacturer of our raw materials, which was included as part of Prepaid and Other Current Assets in our condensed balance sheet. During the first quarter of 2021, the production of raw materials was completed, and ownership was transferred to us. Accordingly, such advance payments were reclassified to inventories as raw materials.

10. Cash, Cash Equivalents and Short-Term Investments

Cash, cash equivalents and short-term investments consisted of the following (in thousands):

	September 30, 2021	December 31, 2020
Cash	$ 2,610	$ 1,988
Money market funds	25,794	19,487
U.S. treasury bills	37,991	10,034
Government-sponsored enterprise securities	14,735	4,920
Corporate bonds and commercial paper	62,016	20,898
	$ 143,146	$ 57,327
Reported as:		
Cash and cash equivalents	$ 30,403	$ 30,373
Short-term investments	112,743	26,954
	$ 143,146	$ 57,327

Cash equivalents and short-term investments include the following securities with gross unrealized gains and losses (in thousands):

September 30, 2021	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. treasury bills	$ 37,985	$ 8	$ (2)	$ 37,991
Government-sponsored enterprise securities	14,734	2	(1)	14,735
Corporate bonds and commercial paper	62,015	5	(4)	62,016
Total	$ 114,734	$ 15	$ (7)	$ 114,742

December 31, 2020	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. treasury bills	$ 10,036	$ —	$ (2)	$ 10,034
Government-sponsored enterprise securities	4,920	—	—	4,920
Corporate bonds and commercial paper	20,900	—	(2)	20,898
Total	$ 35,856	$ —	$ (4)	$ 35,852

As of September 30, 2021 and December 31, 2020, our cash equivalents and short-term investments had a weighted-average time to maturity of approximately 227 days and 78 days, respectively. Our short-term investments are classified as available-for-sale securities. Accordingly, we have classified certain securities as short-term investments on our balance sheets as they are available for use in the current operations. As of September 30, 2021, we had no

investments that had been in a continuous unrealized loss position for more than 12 months. As of September 30, 2021, a total of 19 individual securities had been in an unrealized loss position for 12 months or less, and the losses were determined to be temporary. The gross unrealized losses above were caused by interest rate increases. No significant facts or circumstances have arisen to indicate that there has been any significant deterioration in the creditworthiness of the issuers of the securities held by us. Based on our review of these securities, including the assessment of the duration and severity of the unrealized losses and our ability and intent to hold the investments until maturity, there were no other-than-temporary impairments for these securities as of September 30, 2021.

The following table shows the fair value and gross unrealized losses of our investments in individual securities that are in an unrealized loss position, aggregated by investment category (in thousands):

September 30, 2021	Fair Value	Unrealized Losses
U.S. treasury bills	$ 12,814	$ (2)
Government-sponsored enterprise securities	3,338	(1)
Corporate bonds and commercial paper	22,336	(4)
Total	$ 38,488	$ (7)

11. Fair Value

Under FASB ASC 820, *Fair Value Measurements and Disclosures*, fair value is defined as the price at which an asset could be exchanged, or a liability transferred in a transaction between knowledgeable, willing parties in the principal or most advantageous market for the asset or liability. Where available, fair value is based on observable market prices or parameters or derived from such prices or parameters. Where observable prices or parameters are not available, valuation models are applied.

Assets and liabilities recorded at fair value in our financial statements are categorized based upon the level of judgment associated with the inputs used to measure their fair value. Hierarchical levels directly related to the amount of subjectivity associated with the inputs to fair valuation of these assets and liabilities, are as follows:

Level 1—Inputs are unadjusted, quoted prices in active markets for identical assets at the reporting date. Active markets are those in which transactions for the asset or liability occur in sufficient frequency and volume to provide pricing information on an ongoing basis.

The fair valued assets we hold that are generally included under this Level 1 are money market securities where fair value is based on publicly quoted prices.

Level 2—Inputs, other than quoted prices included in Level 1, that are either directly or indirectly observable for the asset or liability through correlation with market data at the reporting date and for the duration of the instrument's anticipated life.

The fair valued assets we hold that are generally assessed under Level 2 included government-sponsored enterprise securities, U.S. treasury bills and corporate bonds and commercial paper. We utilize third party pricing services in developing fair value measurements where fair value is based on valuation methodologies such as models using observable market inputs, including benchmark yields, reported trades, broker/dealer quotes, bids, offers and other reference data. We use quotes from external pricing service providers and other on-line quotation systems to verify the fair value of investments provided by our third-party pricing service providers. We review independent auditor's reports from our third-party pricing service providers particularly regarding the controls over pricing and valuation of financial instruments and ensure that our internal controls address certain control deficiencies, if any, and complementary user entity controls are in place.

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities and which reflect management's best estimate of what market participants would use in pricing the asset or liability at the reporting date. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model.

We do not have fair valued assets and liabilities classified under Level 3.

Fair Value on a Recurring Basis

Financial assets measured at fair value on a recurring basis are categorized in the tables below based upon the lowest level of significant input to the valuations (in thousands):

	Assets at Fair Value as of September 30, 2021			
	Level 1	Level 2	Level 3	Total
Money market funds	$ 25,794	$ —	$ —	$ 25,794
U.S. treasury bills	—	37,991	—	37,991
Government-sponsored enterprise securities	—	14,735	—	14,735
Corporate bonds and commercial paper	—	62,016	—	62,016
Total	$ 25,794	$ 114,742	$ —	$ 140,536

	Assets at Fair Value as of December 31, 2020			
	Level 1	Level 2	Level 3	Total
Money market funds	$ 19,487	$ —	$ —	$ 19,487
U.S. treasury bills	—	10,034	—	10,034
Government-sponsored enterprise securities	—	4,920	—	4,920
Corporate bonds and commercial paper	—	20,898	—	20,898
Total	$ 19,487	$ 35,852	$ —	$ 55,339

12. Lease Agreements

We currently lease our research and office space under a noncancelable lease agreement with our landlord, Healthpeak Properties, Inc. (formerly known as HCP BTC, LLC), which was originally set to expire in 2018. The lease term provides for renewal option for up to two additional periods of five years each. In July 2017, we exercised our option to extend the term of our lease for another five years through January 2023 and modified the amount of monthly base rent during such renewal period.

In December 2014, we entered into a sublease agreement, which was amended in 2017, with an unrelated third party to occupy approximately 57,000 square feet of our research and office space. In February 2017, we entered into an amendment to the sublease agreement to increase the subleased research and office space for an additional 9,328 square feet under the same term of the sublease. Effective July 2017, the sublease agreement was amended primarily to extend the term of the sublease through January 2023 and modified the monthly base rent to equal the amount we will pay our landlord. Because the future sublease income under the extended sublease agreement is the same as the amount we will pay our landlord, we did not recognize any loss on sublease relative to this amendment. We expect to receive approximately $6.2 million in future sublease income (excluding our subtenant's share of facilities operating expenses) through January 2023.

We recorded rent expense on a straight-line basis for our lease, net of sublease income. For our sublease arrangement which we classified as an operating lease, our loss on the sublease was comprised of the present value of our future payments to our landlord less the present value of our future rent payments expected from our subtenant over the term of the sublease.

As of September 30, 2021 and December 31, 2020, we had operating lease right-of-use asset of $11.8 million and $17.9 million, respectively, and lease liability of $12.9 million and $19.3 million, respectively, in the condensed balance sheet. The weighted average remaining term of our lease as of September 30, 2021 was 1.33 years.

As of September 30, 2021, we received from our landlord leasehold improvement incentives amounting to $563,000 related to leasehold improvements. We record these leasehold improvement incentives as a reduction to operating lease right-of-use asset and lease liability until the lease ends and the asset is transferred.

The components of our operating lease expense were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Fixed operating lease expense	$ 1,340	$ 1,340	$ 4,020	$ 4,020
Variable operating lease expense	259	237	651	704
Total operating lease expense	$ 1,599	$ 1,577	$ 4,671	$ 4,724

Supplemental information related to our operating lease were as follow (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Cash payments included in the measurement of operating lease liabilities	$ 2,529	$ 2,431	$ 7,554	$ 7,263

Supplemental information related to our operating sublease was as follow (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Fixed sublease expense	$ 1,095	$ 1,096	$ 3,285	$ 3,286
Variable sublease expense	236	245	680	742
Sublease income	(1,331)	(1,341)	(3,965)	(4,028)
Net	$ —	$ —	$ —	$ —

The following table presents the future lease payments of our operating lease liabilities as of September 30, 2021 (in thousands):

	Operating Lease	Sublease Receipts	Net
Remainder of 2021	$ 2,529	$ (1,137)	$ 1,392
2022	10,485	(4,716)	5,769
2023	877	(394)	483
Total minimum payments required	$ 13,891	$ (6,247)	$ 7,644

13. Debt

On September 27, 2019 (Closing Date), we entered into a Credit and Security Agreement (Credit Agreement) with MidCap Financial Trust (MidCap). The Credit Agreement provides for a $60.0 million term loan credit facility with the following tranches: (i) on the Closing Date, $10.0 million aggregate principal amount of term loans (Tranche 1), (ii) until December 31, 2020, an additional $10.0 million term loan facility at our option (Tranche 2), (iii) until March 31, 2021, an additional $20.0 million term loan facility subject to the satisfaction of certain conditions and at our option (Tranche 3) and (iv) until March 31, 2022, an additional $20.0 million term loan facility subject to the satisfaction of certain conditions and at our option (Tranche 4). The obligations under the Credit Agreement are secured by a perfected security interest in all of our assets except for intellectual property and certain other customary excluded property pursuant to the terms of the Credit Agreement.

At the Closing Date, $10.0 million was funded in an initial tranche. In March 2020, we signed a credit extension form for Tranche 2 amounting to $10.0 million, which we received in May 2020. In April 2021, we amended the Credit Agreement to extend the period through which Tranche 3 will be available through March 31, 2022, subject to the satisfaction of certain conditions and at our option. To date, the facility gives us the ability to access an additional $40.0 million at our option, subject to the achievement of certain customary conditions.

The outstanding principal balance of the loan bears interest at an annual rate of one-month LIBOR or a comparable applicable index rate determined pursuant to the Credit Agreement. if the LIBOR is no longer available)

plus 5.65%, subject to a LIBOR floor of 1.50% and is payable monthly in arrears. Commencing on October 1, 2019, the Credit Agreement provides that we initially make interest-only payments for 24 months followed by 36 months of amortization payments. The interest-only period can be extended to 36 months and again to 48 months upon the satisfaction of certain conditions set forth in the Credit Agreement.In June 2021, we satisfied the conditions under the Credit Agreement which effectively extended the interest-only period to 36 months or through October 1, 2022. All unpaid principal and accrued interest are due and payable no later than September 1, 2024. A final payment fee of 2.5% of principal is due on the final payment of the term loan.

We may make voluntary prepayments, in whole or in part, subject to certain prepayment premiums and additional interest payments. The Credit Agreement also contains certain provisions, such as event of default and change in control provisions, which, if triggered, would require us to make mandatory prepayments on the term loan, which are subject to certain prepayment premiums and additional interest payments.

As of September 30, 2021 and December 31, 2020, the outstanding balance of the loan, net of unamortized debt discount, was $19.9 million and $19.8 million, respectively. Debt issuance costs are recorded as a direct deduction from the term loan on the balance sheet and are being amortized ratably as interest expense over the term of the loan, using the effective interest method. As of September 30, 2021 and December 31, 2020, the unamortized issuance costs and debt discounts amounted to $113,000 and $185,000, respectively.

For the three and nine months ended September 30, 2021, interest expense, including amortization of the debt discount and accretion of the final fees related to the Credit Agreement was $427,000 and $1.2 million, respectively. For the three and nine months ended September 30, 2020, interest expense, including amortization of the debt discount and accretion of the final fees related to the Credit Agreement was $429,000 and $1.0 million, respectively. Accrued interest of $351,000 was included within other accrued liabilities in the condensed balance sheet as of September 30, 2021.

The following table presents the future minimum principal payments of the outstanding loan as of September 30, 2021 under the current Credit Agreement (in thousands):

Remainder of 2021	$	—
2022		2,500
2023		10,000
2024		7,500
Principal amount (Tranches 1 and 2)	$	20,000

The Credit Agreement contains certain covenants which, among others, require us to deliver financial reports at designated times of the year and maintain minimum net revenues and $10.0 million of cash to draw Tranche 3 or Tranche 4. As of September 30, 2021, we were not in violation of any covenants.

Note 14. Income Taxes

For the three and nine months ended September 30, 2021, we recorded benefit from income tax of $136,000 and provision for income tax of $665,000, respectively. The benefit from and the provision for income tax for the three and nine months ended September 30, 2021 were determined using our effective tax rate on our year-to-date income (loss). We estimated a state tax liability over our pre-tax income (loss) for 2021, which is primarily due to revenue recognized for the Lilly Agreement. We do not expect to owe federal income taxes due to the sufficient net operating loss carryforwards that were generated prior to the enactment of the Tax Cuts and Jobs Act, as well as significant research and development credit carryforwards. We continue to record a full valuation allowance on our deferred tax assets considering our cumulative losses in prior years and forecasted losses in the future. For the three and nine months ended September 30, 2020, we did not record provision for income taxes due to our pre-tax book loss.

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

This discussion and analysis should be read in conjunction with our financial statements and the accompanying notes included in this report and the audited financial statements and accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2020. Our financial results for the three and nine months ended September 30, 2021 are not necessarily indicative of results that may occur in future interim periods or for the full fiscal year.

This Quarterly Report on Form 10-Q contains statements indicating expectations about future performance and other forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (Securities Act) and Section 21E of the Securities Exchange Act of 1934, as amended (Exchange Act), that involve risks and uncertainties. We usually use words such as "may," "will," "would," "should," "could," "expect," "plan," "anticipate," "believe," "estimate," "predict," "intend," or the negative of these terms or similar expressions to identify these forward-looking statements. These statements appear throughout this Quarterly Report on Form 10-Q and are statements regarding our current expectations, beliefs or intent, primarily with respect to our operations and related industry developments. Examples of these statements include, but are not limited to, statements regarding the following: our expectations regarding the impact of the global COVID-19 pandemic; our business and scientific strategies; risks and uncertainties associated with the commercialization and marketing of TAVALISSE in the U.S. and in Europe; risks that the United States Food and Drug Administration (FDA), European Medicines Agency (EMA) or other regulatory authorities may make adverse decisions regarding fostamatinib; the progress of our and our collaborators' product development programs, including clinical testing, and the timing of results thereof; our corporate collaborations and revenues that may be received from our collaborations and the timing of those potential payments; our expectations with respect to regulatory submissions and approvals; our drug discovery technologies; our research and development expenses; protection of our intellectual property; sufficiency of our cash and capital resources and the need for additional capital; and our operations and legal risks. You should not place undue reliance on these forward-looking statements. Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including as a result of the risks and uncertainties discussed under the heading "Risk Factors" in Item 1A of Part II of this Quarterly Report on Form 10-Q. Any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events, except as required by applicable law. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

Overview

We are a biotechnology company dedicated to discovering, developing and providing novel small molecule drugs that significantly improve the lives of patients with hematologic disorders, cancer and rare immune diseases. Our pioneering research focuses on signaling pathways that are critical to disease mechanisms. Our first product approved by the FDA is TAVALISSE® (fostamatinib disodium hexahydrate) tablets, the only oral spleen tyrosine kinase (SYK) inhibitor, for the treatment of adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment. The product is also commercially available in Europe, the United Kingdom (TAVLESSE) and Canada (TAVALISSE) for the treatment of chronic ITP in adult patients.

Fostamatinib is currently being studied in a Phase 3 trial for the treatment of warm autoimmune hemolytic anemia (wAIHA); a Phase 3 clinical trial for the treatment of hospitalized high-risk patients with COVID-19; a National Institute of Health (NIH)/National Heart, Lung, and Blood Institute (NHLBI) sponsored Phase 3 trial (ACTIV-4 Host Tissue Trial) for the treatment of COVID-19 in hospitalized patients; and a Phase 2 trial for the treatment of COVID-19 being conducted by Imperial College London.

Our other clinical programs include our interleukin receptor-associated kinase (IRAK) inhibitor program, and a receptor-interacting serine/threonine-protein kinase (RIP1) inhibitor program in clinical development with partner Eli Lilly and Company (Lilly). In addition, we have product candidates in clinical development with partners AstraZeneca AB (AZ), BerGenBio ASA (BerGenBio) and Daiichi Sankyo (Daiichi).

Business Update

TAVALISSE IN ITP

For the nine months ended September 30, 2021, net product sales of TAVALISSE were $45.4 million, a 3% increase compared to the same period in 2020. The increase in our net product sales was primarily driven by the increase in quantities sold particularly during the second quarter of 2021, as well as the increase in price per bottle of TAVALISSE. Our net product sales during the nine months ended September 30, 2021 however, were negatively impacted by the decrease in level of inventories remaining at our distribution channels at the end of the third quarter of 2021, as well as higher government program rebates. Incrementally, our first quarter 2021 net sales were impacted by the typical first quarter reimbursement issues such as the resetting of co-pays and the Medicare donut hole, along with physician and patient access issues due to COVID-19 pandemic.

Due to the evolving effects of the COVID-19 pandemic, we continue to deploy resources to enable our field-based employees to continue to engage virtually with health care providers. These virtual engagements have enabled our field team to support existing prescribers, as well as develop new prescribers to identify appropriate patients for TAVALISSE. We also conducted market research with chronic ITP prescribers in 2020 to understand the impact of COVID on chronic ITP management. More than half of respondents reported that COVID had an impact on their management of chronic ITP, and about a third of respondents anticipate a surge of patients post-COVID. This is because clinicians have found it challenging to both start a therapy, and switch to new therapies. Starting in 2021, we began to see an increase in in-person engagements with health care providers, while maintaining our level of virtual engagements. During the third quarter of 2021, we expanded our sales force by increasing our territories.

A post-hoc analysis from our Phase 3 clinical program in adult patients with chronic ITP, highlighting the potential benefit of using TAVALISSE in earlier lines of therapy, was published in the British Journal of Haematology in July 2020. Inclusion in one of the leading peer-reviewed journals in the field of hematology underscores the significance of the 78% (25/32) response rate defined as at least one platelet count of at least 50,000/μL when TAVALISSE was used as a second-line therapy in our Phase 3 clinical program. Adverse events were manageable and consistent with those previously reported with fostamatinib. Our sales force is sharing this data with physicians.

Global Strategic Partnership with Lilly

In February 2021, we entered into a global exclusive license agreement and strategic collaboration with Lilly (the Lilly Agreement), to develop and commercialize R552, a RIP1 inhibitor, for the treatment of non-central nervous system (non-CNS) diseases. In addition, the collaboration is aimed at developing additional RIP1 inhibitors for the treatment of central nervous system (CNS) diseases. Pursuant to the terms of the license agreement, we granted to Lilly the exclusive rights to develop and commercialize R552 and related RIP1 inhibitors in all indications worldwide. The parties' collaboration is governed through a joint governance committee and appropriate subcommittees. The agreement became effective in March 2021 upon clearance under the Hart-Scott-Rodino (HSR) Antitrust Improvements Act of 1976.

We are responsible for 20% of development costs for R552 in the U.S., Europe, and Japan, up to a specified cap. Lilly is responsible for funding the remainder of all development activities for R552 and other non-CNS disease development candidates. We have the right to opt- out of co-funding the R552 development activities in the U.S., Europe and Japan at two different specified times. If we exercise our first opt- out right (no later than September 30, 2023), we are required to fund our share of the R552 development activities in the U.S., Europe, and Japan up to a maximum funding commitment of $65.0 million through April 1, 2024. We are responsible for performing and funding initial discovery and identification of CNS disease development candidates. Following candidate selection, Lilly will be responsible for performing and funding all future development and commercialization of the CNS disease development candidates.

Under the terms of the Lilly Agreement, we were entitled to receive an upfront cash payment of $125.0 million, which we received in April 2021, with the potential for an additional $330.0 million in milestone payments upon the achievement of specified development and regulatory milestones by non-CNS disease products and $255.0 million in milestone payments upon the achievement of specified development and regulatory milestones by CNS disease products. We are also eligible to receive up to $100.0 million in sales milestone payments on a product-by-product basis for non-CNS disease products and up to $150.0 million in sales milestone payments on a product-by-product basis for CNS disease products. In addition, depending on the extent of our co-funding of R552 development activities, we would be entitled to receive tiered royalty payments on net sales of non-CNS disease products at percentages ranging from the mid-single digits to high-teens, subject to certain standard reductions and offsets. We would be entitled to receive tiered royalty payments on net sales of CNS disease products up to low-double digits, subject to certain standard reductions and offsets.

Fostamatinib in Hospitalized COVID-19 patients

In April 2021, we reported positive topline results from a multi-center, Phase 2 clinical trial sponsored by the NIH/NHLBI, evaluating the safety of fostamatinib, our oral SYK inhibitor, for the treatment of hospitalized patients with COVID-19. The trial met its primary endpoint of comparable safety than standard of care and showed broad and consistent improvement in numerous efficacy endpoints, including mortality, ordinal scale assessment, and number of days in the ICU. In late-May 2021, the trial data were submitted as part of a request for an Emergency Use Authorization (EUA) from the FDA for the fostamatinib as a treatment for hospitalized patients with COVID-19. In August 2021, the FDA informed us that the clinical data submitted from the NIH/NHLBI-sponsored Phase 2 trial of fostamatinib to treat hospitalized patients suffering from COVID-19 are insufficient to support an EUA. We continue to focus on enrolling patients in our Phase 3 clinical trial and anticipates providing further safety and efficacy data from this larger trial of fostamatinib in COVID-19 patients. If this trial meets its endpoints, we plan to resubmit an application for EUA with this additional data. In September 2021, the data from the NIH/NHLBI-sponsored Phase 2 trial was published in Clinical Infectious Diseases, an official publication of the Infectious Disease Society of America.

In June 2021, we announced that fostamatinib has been selected for NIH ACTIV-4 (Accelerating COVID-19 Therapeutic Inventions and Vaccines) trial in hospitalized patients with COVID-19. The ACTIV-4 Host study, initiated and funded by NHLBI, is a randomized, placebo-controlled trial of therapies, including fostamatinib, targeting the host response to COVID-19 in hospitalized patients. The ACTIV-4 Host Tissue study will evaluate fostamatinib in a population targeted to include approximately 300 hospitalized patients with COVID-19.

Update on Current and Potential Future Impact of COVID-19 on our Business

We are continuing to monitor the impact of the evolving effects of the COVID-19 pandemic and have undertaken, and plan to continue to undertake, safety measures to keep our staff, patients, investigators and stockholders safe and to help the communities where we live and work to reduce the number of people exposed to the virus. Although we have recently initiated the first phase of our return-to-work initiatives, the majority of our employees continue to work remotely. Through our existing Crisis Management Team (CMT), we implemented and continue to monitor our business continuity plans to prevent or minimize business disruption and ensure the safety and well-being of our personnel. Our CMT meets regularly to assess the effectiveness of our business continuity plans and make adjustments accordingly as COVID-19 continues to evolve. The ultimate impact of the COVID-19 pandemic on our business and financial condition is highly uncertain and subject to change, and as such, we cannot ascertain the full extent of the impacts on our sales of our products, our ability to continue to secure new collaborations and support existing collaboration efforts with our partners and our clinical and regulatory activities.

Since the COVID-19 pandemic was declared, we have observed reduced patient-doctor interactions and our representatives are having fewer visits with health care providers, which negatively affected our ability to grow our product sales and may continue to negatively affect our product sales in the future. Resources have been deployed to enable our field team to have virtual engagements to support existing prescribers as well as partner with new prescribers to identify appropriate patients for TAVALISSE. Other commercial related activities, such as our marketing programs, speaker bureaus, and market access initiatives that were in live forums have been conducted virtually, delayed or cancelled as a result of the COVID-19 pandemic. Starting in 2021, we began to see an increase in in-person engagements

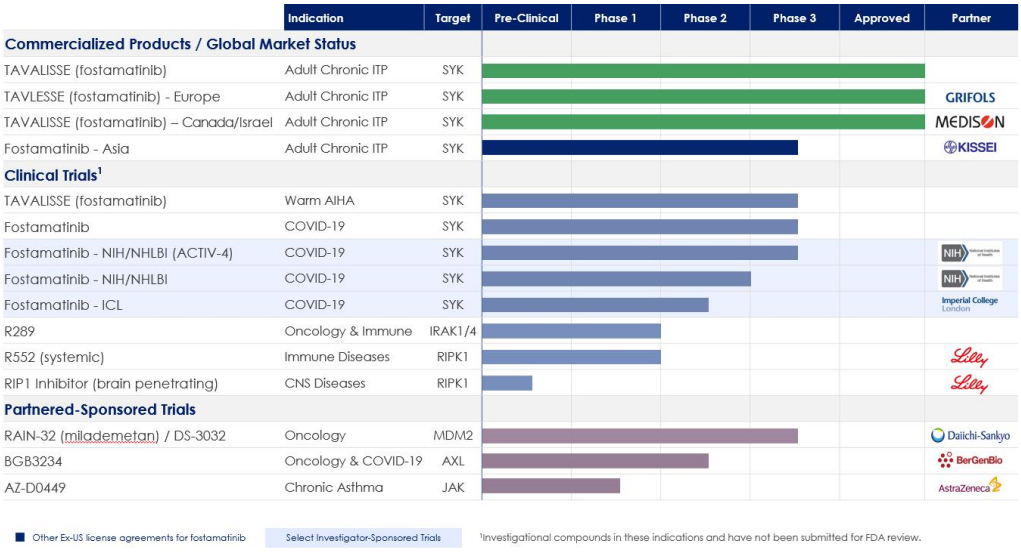
with health care providers. We have plans in place to continue implementing both virtual and live initiatives to ensure we are able to meet the needs of health care providers as the pandemic continues to evolve. Additionally, we recently completed our sales force expansion which increased the territories we cover.

With respect to our supply chain, we currently do not anticipate significant disruption in the supply chain for our commercial product, TAVALISSE. However, we do not know the full extent of the impact on our supply chain if the COVID-19 pandemic continues and persists for an extended period of time.

See also the section titled "Risk Factors" in Item 1A of this Form 10-Q for additional information on risks and uncertainties related to the ongoing COVID-19 pandemic.

Our Product Portfolio

The following table summarizes our portfolio:



Commercial Product

TAVALISSE in ITP

Disease background. Chronic ITP affects an estimated 81,300 adult patients in the U.S. In patients with ITP, the immune system attacks and destroys the body's own blood platelets, which play an active role in blood clotting and healing. ITP patients can suffer extraordinary bruising, bleeding and fatigue as a result of low platelet counts. Current therapies for ITP include steroids, blood platelet production boosters that imitate thrombopoietin (TPOs) and splenectomy.

Orally-available fostamatinib program. Taken in tablet form, fostamatinib blocks the activation of SYK inside immune cells. ITP is typically characterized by the body producing antibodies that attach to healthy platelets in the blood stream. Immune cells recognize these antibodies and affix to them, which activates the SYK enzyme inside the immune cell, and triggers the destruction of the antibody and the attached platelet. When SYK is inhibited by fostamatinib, it interrupts this immune cell function and allows the platelets to escape destruction. The results of our Phase 2 clinical trial, in which fostamatinib was orally administered to 16 adults with chronic ITP, published in *Blood*, showed that fostamatinib significantly increased the platelet counts of certain ITP patients, including those who had failed other currently available agents.

Our Fostamatinib for Immune Thrombocytopenia (FIT) Phase 3 clinical program had a total of 150 ITP patients which were randomized into two identical multi-center, double-blind, placebo-controlled clinical trials. The patients were diagnosed with persistent or chronic ITP, and had blood platelet counts consistently below 30,000 per microliter of blood. Two-thirds of the subjects received fostamatinib orally at 100 mg twice daily bid and the other third received placebo on the same schedule. Subjects were expected to remain on treatment for up to 24 weeks. At week four of treatment, subjects who failed to meet certain platelet counts and met certain tolerability thresholds could have their dosage of fostamatinib (or corresponding placebo) increased to 150 mg bid. The primary efficacy endpoint of this program was a stable platelet response by week 24 with platelet counts at or above 50,000 per microliter of blood for at least four of the final six qualifying blood draws. In August 2015, the FDA granted our request for Orphan Drug designation for fostamatinib for the treatment of ITP.

In August 2016, we announced the results of the first FIT study, reporting that fostamatinib met the study's primary efficacy endpoint. The study showed that 18% of patients receiving fostamatinib achieved a stable platelet response compared to none receiving a placebo control (p=0.0261). In October 2016, we announced the results of the second FIT study, reporting that the response rate was consistent with the first study. In the ITP double-blind studies, the most commonly-reported adverse reactions occurring in at least 5% of patients treated with TAVALISSE were diarrhea, hypertension, nausea, dizziness, increased alanine aminotransferase (ALT), increased aspartate aminotransferase (AST), respiratory infection, rash, abdominal pain, fatigue, chest pain, and neutropenia. Serious adverse drug reactions occurring in at least 1% of patients treated with TAVALISSE in the ITP double-blind studies were febrile neutropenia, diarrhea, pneumonia, and hypertensive crisis.

TAVALISSE was approved by the FDA in April 2018 for the treatment of ITP in adult patients who have had an insufficient response to a previous treatment, and successfully launched in the U.S. in May 2018. In January 2020, the EC granted our Marketing Authorization Application (MAA) in Europe for fostamatinib for the treatment of chronic ITP in adult patients who are refractory to other treatments. In February 2020, Kissei Pharmaceutical Co., Ltd. (Kissei) was granted orphan drug designation from the Japanese Ministry of Health, Labor and Welfare for R788 (fostamatinib) in chronic idiopathic thrombocytopenic purpura.

Commercial activities, including sales and marketing

A significant portion of our business operations was related to our commercial activities for TAVALISSE. Specifically, our marketing and sales efforts are focused on hematologists and hematologist-oncologists in the U.S., who manage chronic adult ITP patients. In July 2020, Grifols S.A. (Grifols) launched TAVLESSE in the United Kingdom (UK) and Germany. In September 2021, Grifols announced that it began commercializing TAVLESSE in France, Italy and Spain. The phased rollout across the rest of Europe planned over the following months will include the Czech Republic, Denmark, Finland, Norway and Sweden.

We have a fully integrated commercial team consisting of sales, marketing, market access, and commercial operations functions. Our sales team promotes TAVALISSE in the U.S. using customary pharmaceutical company practices, and we concentrate our efforts on hematologists and hematologists-oncologists. TAVALISSE is sold initially through third-party wholesale distribution and specialty pharmacy channels and group purchasing organizations before being ultimately prescribed to patients. To facilitate our commercial activities in the U.S., we also enter into arrangements with various third-parties, including advertising agencies, market research firms and other sales-support-related services as needed. We believe that our commercial team and distribution practices are adequate to ensure that our marketing efforts reach relevant customers and deliver our products to patients in a timely and compliant fashion. Also, to help ensure that all eligible patients in the U.S. have appropriate access to TAVALISSE, we have established a

reimbursement and patient support program called Rigel One Care (ROC). Through ROC, we provide co-pay assistance to qualified, commercially insured patients to help minimize out-of-pocket costs and also provide free drug to uninsured or under-insured patients who meet certain established clinical and financial eligibility criteria. In addition, ROC is designed to provide reimbursement support, such as information related to prior authorizations, benefits investigations and appeals.

Competitive landscape for TAVALISSE

Our industry is intensely competitive and subject to rapid and significant technological change. TAVALISSE is competing with other existing therapies. In addition, a number of companies are pursuing the development of pharmaceuticals that target the same diseases and conditions that we are targeting. For example, there are existing therapies and drug candidates in development for the treatment of ITP that may be alternative therapies to TAVALISSE.

Currently, corticosteroids remain the most common first line therapy for ITP, occasionally in conjunction with intravenous immunoglobulin (IVIg) or anti-Rh(D) to help further augment platelet count recovery, particularly in emergency situations. However, it has been estimated that frontline agents lead to durable remissions in only a small percentage of newly-diagnosed adults with ITP. Moreover, concerns with steroid-related side effects often restrict therapy to approximately four weeks. As such, many patients progress to persistent or chronic ITP, requiring other forms of therapeutic intervention. In long-term treatment of chronic ITP, patients are often cycled through several therapies over time in order to maintain a sufficient response to the disease.

Other approaches to treat ITP are varied in their mechanism of action, and there is no consensus about the sequence of their use. Options include splenectomy, thrombopoietin receptor agonists (TPO-RAs) and various immunosuppressants (such as rituximab). The response rate criteria of the above-mentioned options vary, precluding a comparison of response rates for individual therapies.

Even with the above treatment options, a significant number of patients remain severely thrombocytopenic for long durations and are subject to risk of spontaneous or trauma-induced hemorrhage. The addition of fostamatinib to the treatment options could be beneficial since it has a different mechanism of action than any of the therapies that are currently available. Fostamatinib is a potent and relatively selective SYK inhibitor, and its inhibition of Fc receptors and B-cell receptors of signaling pathways make it a potentially broad immunomodulatory agent.

Other products in the U.S. that are approved by the FDA to increase platelet production through binding and TPO receptors on megakaryocyte precursors include PROMACTA® (Novartis International AG (Novartis)), Nplate® (Amgen, Inc.) and DOPTELET® (Swedish Orphan Biovitrum AB).

Fostamatinib in Global Markets

We have entered into various license agreements to commercialize fostamatinib globally. The following describes the arrangements we have in place with Grifols, Kissei and Medison Pharma Trading AG (Medison Canada) and Medison Pharma Ltd. (Medison Israel, and together with Medison Canada, Medison). We retain the global rights to fostamatinib outside of the Grifols, Kissei and Medison territories.

Fostamatinib in Europe/Turkey

In January 2019, we entered into an exclusive commercialization license agreement with Grifols to commercialize fostamatinib for the treatment, palliation, or prevention of human diseases, including chronic or persistent ITP and AIHA in Europe and Turkey. Pursuant to the terms of the license agreement, Grifols has exclusive rights to commercialize, and non-exclusive rights to develop, fostamatinib in Europe and Turkey. Grifols also received an exclusive option to expand the territory under its exclusive and non-exclusive licenses to include the Middle East, North Africa and Russia (including Commonwealth of Independent States). In November 2020, Grifols exercised its option to include these territories under the agreement.

We are responsible for performing and funding certain development activities for fostamatinib for ITP and AIHA and Grifols is responsible for all other development activities for fostamatinib in such territories. We remain

responsible for the manufacture and supply of fostamatinib for all development and commercialization activities under the agreement. Under the terms of the agreement, we received an upfront cash payment of $30.0 million and will be eligible to receive regulatory and commercial milestones of up to $297.5 million. In January 2020, the European Commission granted a MA for fostamatinib for the treatment of chronic ITP in adult patients who are refractory to other treatments. With this approval, we received a $20.0 million non-refundable milestone payment, comprised of a $17.5 million payment due upon MAA approval by the EMA of fostamatinib for the first indication and a $2.5 million creditable advance royalty payment due upon EMA approval of fostamatinib in the first indication. We will also receive tiered royalty payments ranging from the mid-teens to 30% of net sales of fostamatinib in Europe and Turkey.

Fostamatinib in Japan/Asia

In October 2018, we entered into an exclusive license and supply agreement with Kissei to develop and commercialize fostamatinib in all current and potential indications in Japan, China, Taiwan and the Republic of Korea. Kissei is a Japan-based pharmaceutical company addressing patients' unmet medical needs through its research, development and commercialization efforts, as well as through collaborations with partners.

Under the terms of the agreement, we received an upfront cash payment of $33.0 million, with the potential for an additional $147.0 million in development and commercial milestone payments, and will receive product transfer price payments in the mid to upper twenty percent range based on tiered net sales for the exclusive supply of fostamatinib. Kissei receives exclusive rights to fostamatinib in ITP and all future indications in Japan, China, Taiwan, and the Republic of Korea.

In September 2019, Kissei initiated a Phase 3 trial in Japan of fostamatinib in adult patients with chronic ITP. The efficacy and safety of orally administered fostamatinib will be assessed by comparing it with placebo in a randomized, double-blind study. Japan has the third highest prevalence of chronic ITP in the world behind the United States and Europe. In February 2020, Kissei was granted orphan drug designation from the Japanese Ministry of Health, Labor and Welfare for R788 (fostamatinib) in chronic ITP. Kissei has completed the enrollment of its Phase 3 clinical trial of fostamatinib in adult Japanese patients with chronic ITP.

Fostamatinib in Canada/Israel

In October 2019, we entered into exclusive commercial and license agreements with Medison to commercialize fostamatinib in all potential indications in Canada and Israel. Under the terms of the agreements, we received an upfront payment of $5.0 million with the potential for approximately $35.0 million in regulatory and commercial milestones. In addition, we will receive royalty payments beginning at 30% of net sales. Under our agreement with Medison for the Canada territory, we have the option to buy back all rights to the product upon regulatory approval in Canada for the indication of AIHA. The buyback provision if exercised would require both parties to mutually agree on commercially reasonable terms for us to purchase back the rights, taking into account Medison's investment and the value of the rights, among others. Pursuant to this exclusive commercialization license agreement, in August 2020, we entered into a commercial supply agreement with Medison.

In November 2020, Health Canada approved the New Drug Submission for TAVALISSE for the treatment of thrombocytopenia in adult patients with chronic ITP who have had an insufficient response to other treatments. In August 2021, Medison Israel received the licenses for registrational approval from the Ministry of Health, which triggered the first milestone that is the regulatory approval of the product in Israel for the first indication, for a non-refundable payment of $75,000.

Clinical Stage Programs

Fostamatinib—AIHA

Disease background. Autoimmune hemolytic anemia (AIHA) is a rare, serious blood disorder where the immune system produces antibodies that result in the destruction of the body's own red blood cells. Symptoms can include fatigue, shortness of breath, rapid heartbeat, jaundice or enlarged spleen. While no medical treatments are currently approved for AIHA, physicians generally treat acute and chronic cases of the disorder with corticosteroids,

other immuno-suppressants, or splenectomy. Research has shown that inhibiting SYK with fostamatinib may reduce the destruction of red blood cells. This disorder affects an estimated 45,000 Americans, for whom no approved treatment options currently exist.

Orally-available fostamatinib program. We completed our Phase 2 clinical trial, also known as the SOAR study in patients with wAIHA. This trial was an open-label, multi-center, two-stage study that evaluated the efficacy and safety of fostamatinib in patients with wAIHA who had previously received treatment for the disorder but have relapsed. The primary efficacy endpoint of this study was to achieve increased hemoglobin levels by week 12 of greater than 10 g/dL, and greater than or equal to 2 g/dL higher than baseline. In November 2019, we announced updated data that in a Phase 2 open-label study of fostamatinib in patients with wAIHA, data showed that 44% (11/25) of evaluable patients met the primary efficacy endpoint of a Hgb level >10 g/dL with an increase of ≥2 g/dL from baseline by week 24. Including one late responder at week 30, the overall response rate was 48% (12/25). Adverse events were manageable and consistent with those previously reported with fostamatinib.

In March 2019, we initiated our wAIHA pivotal Phase 3 clinical study of fostamatinib, known as FORWARD study. The clinical trial protocol calls for a placebo-controlled study of approximately 90 patients with primary or secondary wAIHA who have failed at least one prior treatment. The primary endpoint will be a durable Hgb response, defined as Hgb > 10 g/dL and > 2 g/dL increase from baseline and durability measure, with the response not being attributed to rescue therapy. To date, we completed the enrollment of this study. Following the six-month treatment period after the last patient enrollment, we expect to report topline data from the 24-week study in mid-2022 and proceed with regulatory filings if the data is positive. If approved, TAVALISSE has the potential to be the first to market therapy for patients with wAIHA.

In November 2020, we reached an agreement with the FDA on the durable response measure for the primary efficacy endpoint of the study as well as the inclusion of additional secondary endpoints. In January 2021, we announced that the FDA had granted Fast Track designation to TAVALISSE for the treatment of wAIHA. The FDA previously granted TAVALISSE Orphan Drug designation for the treatment of wAIHA in January 2018.

Fostamatinib—in Hospitalized COVID-19 Patients

Disease background. COVID-19 is the infectious disease caused by Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2). SARS-CoV-2 primarily infects the upper and lower respiratory tract and can lead to acute respiratory distress syndrome (ARDS). Additionally, some patients develop other organ dysfunction including myocardial injury, acute kidney injury, shock resulting in endothelial dysfunction and subsequently micro and macrovascular thrombosis. Much of the underlying pathology of SARS-CoV-2 is thought to be secondary to a hyperinflammatory immune response associated with increased risk of thrombosis. SYK is involved in the intracellular signaling pathways of many different immune cells. Therefore, SYK inhibition may improve outcomes in patients with COVID-19 via inhibition of key Fc gamma receptor (FcγR) and c-type lectin receptor (CLR) mediated drivers of pathology such as inflammatory cytokine release by monocytes and macrophages, production of NETs by neutrophils, and platelet aggregation. Furthermore, SYK inhibition in neutrophils and platelets may lead to decreased thromboinflammation, alleviating organ dysfunction in critically ill patients with COVID-19.

Rigel-led Phase 3 Trial. In November 2020, we launched a Phase 3 clinical trial to evaluate the safety and efficacy of fostamatinib in hospitalized COVID-19 patients without respiratory failure that have certain high-risk prognostic factors. We were awarded $16.5 million from the U.S. Department of Defense's (DOD) Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) to support this Phase 3 clinical trial. This multi-center, double-blind, placebo-controlled, adaptive design study will randomly assign either fostamatinib plus SOC or matched placebo plus SOC (1:1) to 308 targeted evaluable patients. Treatment will be administered orally twice daily for 14 days with follow up to day 60. The primary endpoint of this study is the proportion of subjects who progress to severe/critical disease within 29 days. As of November 1, 2021, we enrolled approximately 210 of the targeted 300 patients.

NIH/NHLBI-sponsored Phase 2 Trial. In September 2020, we announced a Phase 2 clinical trial sponsored by the NIH/NHLBI in order to evaluate the safety of fostamatinib for the treatment of hospitalized COVID-19 patients. This multi-center, double-blind, placebo-controlled study randomly assigned fostamatinib or matched placebo (1:1) to 59

evaluable patients. Treatment was administered orally twice daily for 14 days, and a follow-up period to day 60.The primary endpoint of this study was cumulative incidence of SAE through day 29. The trial also included multiple secondary endpoints designed to assess the early efficacy and clinically relevant endpoints of disease course. The study completed the enrollment in March 2021 and in April 2021, we announced that this Phase 2 clinical trial met its primary endpoint of safety. In September 2021, the data from the NIH/NHLBI-Sponsored Phase 2 trial was published in Clinical Infectious Diseases, an official publication of the Infectious Disease Society of America.

Key findings within the fostamatinib Phase 2 trial include:

- The study met the primary endpoint showing fostamatinib did not increase the incidence of serious adverse events (SAEs) compared with placebo.
- The overall incidence of SAEs by Day 29 was approximately 50% less in the fostamatinib group (10.5%) compared with the placebo group (22.0%) (p=0.2). The most frequent SAE reported by Day 29 was hypoxia, occurring in 1 patient receiving fostamatinib and 3 patients receiving placebo.
- At Day 29, in the overall population there were zero deaths in the fostamatinib group of 30 patients compared to three deaths in the placebo group of 29 patients (p=0.07). In more severe patients, those with an ordinal scale assessment of 6 or 7, the difference was zero of nineteen patients compared to three of seventeen patients (p=0.049), respectively.
- There were four intubated patients in the trial on mechanical ventilation (ordinal scale 7) with two patients randomized to each treatment group. Both patients in the fostamatinib group improved within 7 days and came off the ventilator, while both patients in the placebo group deceased.
- The median number of days in the ICU was reduced by 4 days, from 7 days in the placebo group to 3 days in the fostamatinib group (p=0.07).
- The median number of days on oxygen was 8 in the fostamatinib group compared to 20 in the placebo group (p=0.2). The difference was even greater in more severe patients with the fostamatinib group at 10 days compared to placebo at 28 days (p=0.027).
- At Day 15, 65.5% of patients were free of supplemental oxygen in the fostamatinib group compared to 39.9% in the placebo group (p=0.08). In more severe patients, the difference was 57.9% compared to 20% (p=0.016).
- Fostamatinib was superior to placebo in accelerating improvement in clinical status by day 15 (mean change -3.6 compared to -2.6, p=0.035) and by day 29 (mean change -4.2 compared to -3.3, p=0.12) using ordinal scale assessments.
- The median time to recovery was 8 days in both groups. The greatest benefits were observed in more severe patients where the median time to recovery was reduced from 13 days in the placebo group to 10 days in the fostamatinib group.
- Despite general SOC use of both steroids and remdesivir in all 59 patients, there was a greater reduction in NETosis and other inflammatory biomarkers (CRP, Ferritin, D-Dimer, Fibrinogen) at most timepoints in the fostamatinib group as compared to the placebo group.

In May 2021, the NIH/NHLBI Phase 2 clinical data were submitted as part of a request for EUA from the FDA for fostamatinib as a treatment for hospitalized patients with COVID-19. In August 2021, the FDA informed us that the clinical data submitted from the NIH/NHLBI-sponsored Phase 2 trial of fostamatinib to treat hospitalized patients suffering from COVID-19 was insufficient for EUA. We continue to focus on enrolling patients in our Rigel-led Phase 3 clinical trial. We anticipate providing further safety and efficacy data from this larger trial of fostamatinib in COVID-19 patients. If this trial meets its endpoints, we plan to resubmit our EUA application with this additional data.

ACTIV-4 Host Tissue Phase 3 Trial. Following the completed NIH/NHLBI-sponsored Phase 2 study as discussed above, in June 2021, we announced that fostamatinib has been selected for an NIH ACTIV-4 (Accelerating COVID-19 Therapeutic Inventions and Vaccines) trial in hospitalized patients with COVID-19. The ACTIV-4 Host

study, initiated and funded by NHLBI, is a randomized, placebo-controlled trial of therapies, including fostamatinib, targeting the host response to COVID-19 in hospitalized patients. The master protocol for this study is designed to be flexible in the number of study arms, the use of a single placebo group, and the stopping and adding of new therapies. Each active arm will include approximately 300 patients. Eligible participants will include patients hospitalized for COVID-19 with laboratory-confirmed SARS-CoV-2 infection on oxygen therapy. The primary outcome is oxygen-free days through day 28. Secondary outcomes include hospital mortality, use of mechanical ventilation, and severity of disease as measured by World Health Organization scale scores.

Imperial College of London Phase 2 Trial. In July 2020, we announced a Phase 2 clinical trial sponsored by Imperial College London to evaluate the efficacy of fostamatinib for the treatment of COVID-19 pneumonia. This is a two-stage, open label, controlled clinical trial with patients randomized (1:1:1) to fostamatinib plus SOC, ruxolitinib plus SOC, or standard of care alone. Treatment will be administered twice daily for 14 days and patients will receive a follow-up assessment at day 14 and day 28 after the first dose. The primary endpoint of this study is progression from mild to severe COVID-19 pneumonia within 14 days in hospitalized patients. In November 2020, we announced that the Imperial College London-sponsored clinical trial began enrolling patients, and we are currently enrolling patients under this study.

Other Publications. Researchers at MIT and Harvard led a screen to identify FDA-approved compounds that reduce MUC1 protein abundance. MUC1 is a biomarker used to predict the development of ALI and ARDS and correlates with poor clinical outcomes. In June 2020, the results were presented, and of the 3,713 compounds that were screened, fostamatinib was the only compound identified which both decreased expression of MUC1 and is FDA approved. Fostamatinib demonstrated preferential depletion of MUC1 from epithelial cells without affecting cell viability. The research was focused on drug repurposing for the much lower risk of toxicity and the ability of FDA-approved treatments to be delivered on a shortened timescale, which is critical for patients afflicted with lung disease resulting from COVID-19.

In addition, the in vitro studies led by the Amsterdam University Medical Center at the University of Amsterdam, showed that R406, the active metabolite of fostamatinib, blocked macrophage hyperinflammatory responses to a combination of immune complexes formed by anti-Spike IgG in serum from severe COVID-19 patients. Anti-Spike IgG levels are known to correlate with the severity of COVID-19. These results, presented in July 2020, suggest that by inhibiting anti-Spike IgG-mediated hyperinflammation, R406 could potentially play a role in the prevention of cytokine storms as well as pulmonary edema and thrombosis associated with severe COVID-19.

In December 2020, the Journal of Infectious Diseases published research from NIH which demonstrated that R406, the active metabolite of fostamatinib, was able to inhibit NETosis ex vivo in donor plasma from patients with COVID-19. NETosis is a unique type of cell death resulting in the release of NETs. NETs contribute to thromboinflammation and have been associated with mortality in COVID-19. These data provide insights for how fostamatinib may mitigate neutrophil-associated mechanisms contributing to COVID-19 immunopathogenesis.

R835, an Oral IRAK1/4 Inhibitor for Autoimmune, Inflammatory and Hematology-Oncology Diseases

Orally Available IRAK 1/4 Inhibitor Program. During the second quarter of 2018, we selected R835, a proprietary molecule from our IRAK 1/4 preclinical development program, for human clinical trials. This investigational candidate was an orally administered, potent and selective inhibitor of IRAK1 and IRAK4 that blocks inflammatory cytokine production in response to toll-like receptor (TLR) and the interleukin-1 (IL-1R) family receptor signaling. TLRs and IL-1Rs play a critical role in the innate immune response and dysregulation of these pathways can lead to a variety of inflammatory conditions including psoriasis, rheumatoid arthritis, inflammatory bowel disease and gout (among others). R835 prevents cytokine release in response to TLR and IL-1R activation in vitro. R835 is active in multiple rodent models of inflammatory disease including psoriasis, arthritis, lupus, multiple sclerosis and gout. Preclinical studies show that R835 inhibits both the IRAK1 and IRAK4 signaling pathways, which play a key role in inflammation and immune responses to tissue damage. Dual inhibition of IRAK1 and IRAK4 allows for more complete suppression of pro-inflammatory cytokine release.

In October 2019, we announced results from a Phase 1 clinical trial of R835 in healthy subjects to assess safety, tolerability, PK and pharmacodynamics. The Phase 1 study was a randomized, placebo-controlled, double-blind trial in

91 healthy subjects, ages 18 to 55. The Phase 1 trial showed positive tolerability and PK data as well as established proof-of-mechanism by demonstrating the inhibition of inflammatory cytokine production in response to a lipopolysaccharide (LPS) challenge.

We continue to advance the development of our IRAK1/4 program, recently completing the evaluation of a new pro-drug formulation of R835, R289, in single-ascending and multiple ascending dose studies with positive results. Recent feedback received from FDA on our clinical program to explore R289 in low-risk myelodysplastic syndromes (MDS), is being incorporated into a clinical trial design. In June 2021, we entered into a research collaboration with MD Anderson Cancer Center to evaluate novel IRAK 1/4 inhibitors in a series of preclinical studies of MDS and chronic myelomonocytic leukemia (CMML). The translational research generated from these studies will add to the body of data generated to-date on R835 and further elucidate the therapeutic potential of targeting deregulated innate immune signaling in MDS and CMML. In other immune diseases, we are exploring opportunities including palmoplantar pustulosis (PPP), hidradenitis suppurativa (HS), and others.

Partnered Clinical Programs

BGB324 – BerGenBio

We have an exclusive, worldwide research, development and commercialization agreement with BerGenBio for our investigational AXL receptor tyrosine kinase (AXL) inhibitor, BGB324/R428 (now referred to as bemcentinib).

The product is being investigated in two Phase 2 clinical trials for the treatment of hospitalized patients with COVID-19. Clinical trials are also ongoing across oncology indications with high unmet medical need including acute myeloid leukemia (AML), myelodysplastic syndrome (MDS), and non-small cell lung cancer (NSCLC).

DS-3032 - Daiichi

DS-3032 is an investigational oral selective inhibitor of the murine double minute 2 (MDM2) protein investigated by Daiichi in three Phase 1 clinical trials for solid and hematological malignancies including AML, acute lymphocytic leukemia, chronic myeloid leukemia in blast phase, lymphoma and MDS. Preliminary safety and efficacy data from a Phase 1 study of DS-3032 suggests that DS-3032 may be a promising treatment for hematological malignancies including relapsed/refractory AML and high-risk MDS.

In September 2020, worldwide rights to DS-3032 were out-licensed from Daiichi to Rain Therapeutics Inc. (Rain). In July 2021, Rain announced that it initiated the Phase 3 study that will evaluate the efficacy and safety of milademetan (RAIN-32), a MDM2 inhibitor, for the treatment of de-differentiated liposarcoma, a rare cancer originating from fat cells located in the soft tissues of the body. Rain also plans to commence two additional Phase 2 trials for RAIN-32 in late 2021 or early 2022, an open-label MDM2-amplified tumor-agnostic basket trial and an open-label trial in patients with intimal sarcoma, a rare sarcoma also exhibiting MDM2-amplification.

AZ-D0449 – AZ

We have an agreement with AZ for exclusive, worldwide rights to develop and commercialize our proprietary JAK inhibitor. The JAK inhibitor, R256 (AZ-D099) is being pursued in patients with chronic asthma. In preclinical studies, this molecule was shown to be a potent inhibitor of IL-13 and IL-4 signaling. Inhibiting the IL-13 and IL-14 pathways could reduce the severity of inflammation and improve lung function by mechanisms associated with several hallmarks of asthma such as bronchoconstriction, mucus overproduction and airway remodeling.

AZ is currently conducting a Phase 1 study in healthy volunteers and patients with mild asthma to investigate the safety, anti-inflammatory effect of inhaled AZ-D0449. The study, which follows the single and multiple ascending doses, has completed its enrollment.

Research/Preclinical Programs

We are conducting proprietary research in the broad disease areas of inflammation/immunology, immuno-oncology and cancers. Within these disease areas, our researchers are investigating mechanisms of action as well as screening compounds against potential novel targets and optimizing those leads that appear to have the greatest potential.

Commercialization and Sponsored Research and License Agreements

For a discussion of our Sponsored Research and License Agreements and Government Contract, see Note 8 to our "Notes to Condensed Financial Statements" contained in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Results of Operations

Three and Nine months Ended September 30, 2021 and 2020

Revenues

	Three Months Ended September 30,		Aggregate Change	Nine Months Ended September 30,		Aggregate Change
	2021	2020		2021	2020	
		(in thousands)			(in thousands)	
Product sales, net	$ 16,012	$ 16,289	$ (277)	$ 45,441	$ 43,943	$ 1,498
Contract revenues from collaborations	4,531	2,100	2,431	73,886	46,228	27,658
Government contract	1,000	—	1,000	9,500	—	9,500
Total revenues	$ 21,543	$ 18,389	$ 3,154	$ 128,827	$ 90,171	$ 38,656

The following table summarizes the percentages of revenues from each of our customers who individually accounted for 10% or more (wherein * denotes less than 10%) of the total net product sales and revenues from collaborations:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
ASD Healthcare and Oncology Supply	25%	48%	15%	26%
McKesson Specialty Care Distribution Corporation	35%	34%	17%	20%
Lilly	12%	—	56%	—
Cardinal Healthcare	18%	*	*	*
Grifols	*	*	*	49%
Daiichi	*	11%	*	*

Product sales during the three and nine months ended September 30, 2021 and 2020 were related to sales of TAVALISSE in the U.S. TAVALISSE has been prescribed across all lines of therapy in steroid refractory patients in ITP. It has been utilized by an increasingly broad base of prescribers and community physicians, with growing early line use and strong refill rates. We recognize product sales, net of discounts and allowances. For the three and nine months ended September 30, 2021, our net product sales of TAVALISSE decreased by 2% and increased by 3%, respectively, compared to the same periods in 2020. Our net product sales for the three months ended September 30, 2021 decreased compared to the same period in 2020 mainly due to lower quantities sold, negatively impacted by the decrease in level of inventories remaining at our distribution channels, as well as higher government program rebates. For the nine months ended September 30, 2021, our net product sales increased compared to the same period in 2020 primarily driven by the increase in quantities sold particularly during the second quarter of 2021, as well as the increase in price per bottle of TAVALISSE. Our net product sales during the nine months ended September 30, 2021, however, were negatively impacted by the decrease in level of inventories remaining at our distribution channels at the end of the third quarter of 2021, as well as higher government program rebates. Incrementally, our first quarter 2021 net sales were impacted by the typical first quarter reimbursement issues such as the resetting of co-pays and the Medicare donut hole, along with physician and patient access issues due to COVID-19 pandemic.

Contract revenues from collaborations of $4.5 million in the three months ended September 30, 2021 were comprised of $2.4 million in revenue related to our license agreement with Lilly, $1.8 million in revenue related to a milestone payment under our collaboration agreement with Daiichi, $225,000 in revenue related to the research and development services with Grifols and $75,000 milestone payment under our commercial and license agreement with Medison. Contract revenues from collaborations of $73.9 million in the nine months ended September 30, 2021 were comprised of $66.4 million revenue related to our license agreement with Lilly, $4.0 million revenue related to grant of

non-exclusive license of a certain patent to an unrelated third-party company, $1.8 million in revenue related to the achievement of milestone under our collaboration agreement with Daiichi, $1.0 million revenue for the delivery of drug supply under our collaboration agreement with Grifols, $605,000 in revenue related to the research and development services with Grifols and $75,000 milestone payment under our commercial and license agreement with Medison.

Contract revenues from collaborations of $2.1 million in the three months ended September 30, 2020 was related to a milestone payment under our collaboration agreement with Daiichi. Contract revenues from collaborations of $46.2 million in the nine months ended September 30, 2020 comprised of $44.1 million revenue recognized from Grifols related to the upfront fee previously in the first quarter of 2019 and the milestone payment received in the first quarter of 2020 upon EC approval of the MAA for fostamatinib in Europe, and the $2.1 million in revenue from the milestone payment under our collaboration agreement with Daiichi.

Government contract revenue for the three and nine months ended September 30, 2021 of $1.0 million and $9.5 million, respectively, were related to the income we recognized from the $16.5 million government award granted to us, pursuant to the agreement we entered in January 2021 with the U.S. Department of Defense to support our ongoing Phase 3 clinical trial to evaluate the safety and efficacy of fostamatinib in hospitalized COVID-19 patients. We expect to receive the remaining award of $7.0 million and will recognize as income throughout the period we conduct our clinical trial, when there is reasonable assurance that the conditions of the grant will be met, and the grant will be received.

Our potential future revenues may include product sales from TAVALISSE, payments from our current partners and from new partners with whom we enter into agreements in the future, if any, the timing and amount of which is unknown at this time. We cannot currently fully forecast the extent of the impacts that the COVID-19 pandemic may have on our product sales. As of September 30, 2021, we had deferred revenues of $3.2 million, which we will recognize as revenue upon satisfaction of our remaining performance obligations under our respective collaboration agreements.

Cost of Product Sales

	Three Months Ended September 30,		Aggregate Change	Nine Months Ended September 30,		Aggregate Change
	2021	2020		2021	2020	
		(in thousands)			(in thousands)	
Cost of product sales	$ 151	$ 140	$ 11	$ 596	$ 574	$ 22

The cost of product sales during the three and nine months ended September 30, 2021 and 2020 were related to our product, TAVALISSE. Prior to the FDA approval, manufacturing and related costs were charged to research and development expense. Therefore, these costs were not capitalized and as a result, are not fully reflected in the costs of product sales during the three months ended September 30, 2021 and 2020. We expect we will continue to have a lower cost of product sales that excludes the cost of the active pharmaceutical ingredient (API) that was produced prior to FDA approval until we sell TAVALISSE that includes newly manufactured API. We expect that this will be the case for the near-term and as a result, our cost of product sales will be less than we anticipate it will be in future periods. As we produce TAVALISSE in the future, our inventory cost in the Balance Sheet and Cost of Product Sales will increase reflecting the full cost of manufacturing. The cost of product sales remained flat for the three and nine months ended September 30, 2021 compared to the same periods in 2020.

Research and Development Expense

	Three Months Ended September 30,		Aggregate Change	Nine Months Ended September 30,		Aggregate Change
	2021	2020		2021	2020	
		(in thousands)			(in thousands)	
Research and development expense	$ 18,300	$ 14,600	$ 3,700	$ 51,933	$ 44,963	$ 6,970
Stock-based compensation expense included in research and development expense	$ 402	$ 532	$ (130)	$ 1,522	$ 1,684	$ (162)

The increase in research and development expense for the three months ended September 30, 2021, compared to the same period in 2020, was primarily due to the increases in research and development costs related to our ongoing Phase 3 clinical trial on hospitalized COVID-19 patients of $3.8 million and development of our IRAK 1/4 inhibitor program of $1.3 million. These increases were partially offset by decrease due to the completion of clinical trial in our RIP1 inhibitor program of $1.2 million and decrease in research and development costs in our other clinical studies of $200,000.

The increase in research and development expense for the nine months ended September 30, 2021, compared to the same period in 2020, was primarily due to the increase in research and development costs related to our ongoing Phase 3 clinical trial on hospitalized COVID-19 patients of $10.2 million, development of our IRAK 1/4 inhibitor program of $2.3 million, and other research and development costs in our other clinical studies of $670,000. These increases were partially offset by decrease due to the completion of clinical trial in our RIP1 inhibitor program of $6.2 million.

Our research and development expenditures include costs related to preclinical and clinical trials, scientific personnel, supplies, equipment, consultants, sponsored research, stock-based compensation, and allocated facility costs.

We expect our research and development expense for the remainder of 2021 to increase as we continue our activities in our Phase 3 wAIHA and COVID-19 studies. To date, we completed the enrollment of wAIHA study. Following the six-month treatment period after the last patient enrollment, we expect to report topline data from the 24-week study in mid-2022 and proceed with regulatory filings if the data is positive. We also continue to enroll patients in our Phase 3 clinical trial of fostamatinib for the treatment of hospitalized high-risk patients with COVID-19. The $16.5 million grant awarded by the Department of Defense in January 2021 will partially fund our Phase 3 clinical trial for hospitalized COVID-19 patients. We cannot currently fully forecast the scope the evolving effects of COVID-19 pandemic may have on our ability to continue to treat patients enrolled in our trials, enroll and assess new patients, supply study drug, obtain complete data points in accordance with the study protocol, and overall impact on, and timing of, clinical study results.

We do not track fully burdened research and development costs separately for each of our drug candidates. We review our research and development expenses by focusing on three categories: research, development, and other. Our research team is focused on creating a portfolio of product candidates that can be developed into small molecule therapeutics in our own proprietary programs or with potential collaborative partners and utilizes our robust discovery engine to rapidly discover and validate new product candidates in our focused range of therapeutic indications. “Research” expenses relate primarily to personnel expenses, lab supplies, fees to third party research consultants and compounds. Our development group leads the implementation of our clinical and regulatory strategies and prioritizes disease indications in which our compounds may be studied in clinical trials. “Development” expenses relate primarily to clinical trials, personnel expenses, costs related to the submission and management of our NDA, lab supplies and fees to third party research consultants. “Other” expenses primarily consist of allocated facilities costs and allocated stock-based compensation expense relating to personnel in research and development groups.

In addition to reviewing the three categories of research and development expenses described in the preceding paragraph, we principally consider qualitative factors in making decisions regarding our research and development programs, which include enrollment in clinical trials and the results thereof, the clinical and commercial potential for our drug candidates and competitive dynamics. We also make our research and development decisions in the context of our overall business strategy, which includes the evaluation of potential collaborations for the development of our drug candidates.

We do not have reliable estimates regarding the timing of our clinical trials. Preclinical testing and clinical development are long, expensive and uncertain processes. In general, biopharmaceutical development involves a series of steps, beginning with identification of a potential target and including, among others, proof of concept in animals and Phase 1, 2 and 3 clinical trials in humans. Significant delays in clinical testing could materially impact our product development costs and timing of completion of the clinical trials. We do not know whether planned clinical trials will begin on time, will need to be halted or revamped or will be completed on schedule, or at all. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a trial, delays from scale up, delays in reaching agreement on acceptable clinical trial agreement terms with prospective clinical sites, delays in obtaining institutional review board approval to conduct a clinical trial at a prospective clinical site or delays in recruiting subjects to participate in a clinical trial.

We currently do not have reliable estimates of total costs for a particular drug candidate to reach the market. Our potential products are subject to a lengthy and uncertain regulatory process that may involve unanticipated additional clinical trials and may not result in receipt of the necessary regulatory approvals. Failure to receive the necessary regulatory approvals would prevent us from commercializing the product candidates affected. In addition, clinical trials of our potential products may fail to demonstrate safety and efficacy, which could prevent or significantly delay regulatory approval.

The following table presents our total research and development expense by category (in thousands).

	Three Months Ended September 30,		Nine Months Ended September 30,		From January 1, 2007* to September 30, 2021
	2021	2020	2021	2020	
Categories:					
Research	$ 2,220	$ 2,295	$ 6,994	$ 7,126	$ 263,031
Development	14,155	10,308	38,891	31,668	486,653
Other	1,925	1,997	6,048	6,169	260,999
	$ 18,300	$ 14,600	$ 51,933	$ 44,963	$ 1,010,683

* We started tracking research and development expense by category on January 1, 2007.

"Other" expenses for the three months ended September 30, 2021 and 2020 consisted of allocated facilities costs of $1.5 million for both periods, and allocated stock-based compensation expense of $402,000 and $532,000, respectively. For the nine months ended September 30, 2021 and 2020, "other" expenses include allocated facilities costs of $4.5 million for both periods, and allocated stock-based compensation expense of $1.5 million and $1.7 million, respectively.

For the three and nine months ended September 30, 2021, a major portion of our total research and development expense was associated with our COVID-19, AIHA and IRAK programs, personnel-related costs of our research and development personnel and allocated facilities costs. For the three and nine months ended September 30, 2020, a major portion of our total research and development expense was associated with our AIHA, RIP1, and IRAK programs, personnel-related costs of our research and development personnel and allocated facilities costs.

Selling, General and Administrative Expense

	Three Months Ended September 30,		Aggregate Change	Nine Months Ended September 30,		Aggregate Change
	2021	2020		2021	2020	
		(in thousands)			(in thousands)	
Selling, general and administrative expense	$ 22,877	$ 17,430	$ 5,447	$ 67,376	$ 54,780	$ 12,596
Stock-based compensation expense included in selling, general and administrative expense	$ 1,800	$ 1,352	$ 448	$ 5,625	$ 3,981	$ 1,644

The increase in selling, general and administrative expense for the three months ended September 30, 2021 compared to the same period in 2020 was primarily due to the increases in costs of commercial activities of $2.5 million, consultants and third-party services of $1.5 million, personnel-related costs of $408,000, stock-based compensation expense of $448,000, and other various sales, general and administrative costs of $591,000.

The increase in selling, general and administrative expense for the nine months ended September 30, 2021 compared to the same period in 2020 was primarily due to the increases in costs of consultants and third-party services of $4.6 million, costs of commercial activities of $3.1 million, personnel-related costs of $1.5 million, stock-based compensation expense of $1.6 million, professional fees of $465,000, and other various sales, general and administrative costs of $1.3 million.

We expect our selling, general and administrative expense for the remainder of 2021 to increase as we continue to expand our commercial activities, including the effect of the recent sales force expansion. In response to the limitations on in-person office visits during the ongoing COVID-19 pandemic, we continue to deploy resources to enable our field-based employees to continue to engage virtually with healthcare providers. These virtual engagements have enabled our field team to support existing prescribers as well as partner with new prescribers to identify appropriate patients for our product. However, we are not currently able to fully forecast the scope of impacts that the COVID-19 pandemic may have on our commercial activities and sales of our product.

Interest Income

	Three Months Ended September 30,		Aggregate Change	Nine Months Ended September 30,		Aggregate Change
	2021	2020		2021	2020	
		(in thousands)			(in thousands)	
Interest income	$ 14	$ 36	$ (22)	$ 31	$ 563	$ (532)

Interest income results from our interest-bearing cash and investment balances. The decreases in interest income for the three and nine months ended September 30, 2021 as compared to the same periods in 2020 were primarily due to decrease in interest rates on our investments.

Interest Expense

	Three Months Ended September 30,		Aggregate Change	Nine Months Ended September 30,		Aggregate Change
	2021	2020		2021	2020	
		(in thousands)			(in thousands)	
Interest expense	$ (1,317)	$ (429)	$ (888)	$ (3,561)	$ (924)	$ (2,637)

Interest expense for the three and nine months ended September 30, 2021 was comprised of interest on the financing liability from our collaboration partners Lilly and Medison, and interest on outstanding balance on our term loan from Midcap. Interest expense for the three and nine months ended September 30, 2020 was related to the outstanding balance on our term loan from Midcap. The increase in interest expense in the three and nine months ended September 30, 2021 compared with the same periods in 2020 was mainly due to the interest expense associated with the financing liability from our collaboration partners amounting to $886,000 and $2.3 million, respectively. Incrementally, interest expense increased due to the increase in the outstanding term loan credit balance. The principal balance of loan prior to May 2020 was the initial $10.0 million under Tranche 1. In May 2020, we accessed the Tranche 2 for an additional $10.0 million loan. See Note 13 to our "Notes to Condensed Financial Statements" in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Provision for Income Taxes

	Three Months Ended September 30,		Aggregate Change	Nine Months Ended September 30,		Aggregate Change
	2021	2020		2021	2020	
		(in thousands)			(in thousands)	
Provision for (benefit from) income taxes	$ (136)	$ —	$ (136)	$ 665	—	$ 665

The benefit from and the provision for income taxes for the three and nine months ended September 30, 2021 were determined using our effective tax rate on our year-to-date income (loss). We estimated a state tax liability over our pre-tax income (loss) for 2021, and is primarily due to revenue recognized for the Lilly Agreement. We do not expect to owe federal income taxes due to the sufficient net operating loss (NOL) carryforwards that were generated prior to the enactment of the Tax Cuts and Jobs Act (Tax Act), as well as significant research and development credit carryforwards. We continue to record a full valuation allowance on our deferred tax assets considering our cumulative losses in prior years and forecasted losses in the future. For the three and nine months ended September 30, 2020, we did not record provision for income taxes due to our pre-tax book loss.

Critical Accounting Policies and the Use of Estimates

Our discussion and analysis of our financial condition and results of operations is based upon our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP). The preparation of these financial statements requires us to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, we evaluate our estimates, including any potential impact of the COVID-19 pandemic to the carrying values of our assets and liabilities, those related to revenue recognition on product sales and collaboration agreements, recoverability of our assets, including accounts receivables and inventories, stock-based compensation, the probability of achievement of corporate performance-based milestone for our performance-based stock option awards, impairment issues, the estimated useful life of assets, estimated accruals, particularly research and development accruals, estimates related our valuation of the operating lease right-of-use asset and lease liability, including the incremental borrowing rate used, and net present value of our liability related to our share in the development costs under the Lilly Agreement, including the applicable discount rate. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that there have been no significant changes in our critical accounting policies and estimates disclosed in our Annual Report on Form 10-K for the year ended December 31, 2020, as filed with the Securities and Exchange Commission (SEC).

Recent Accounting Pronouncements

We adopted ASU 2019-12, *Income Taxes (Topic 740) Simplifying the Accounting for Income Taxes,* in the first quarter of 2021. See Note 3 to our "Notes to Condensed Financial Statements" contained in Part I, Item 1 of this Quarterly Report on Form 10-Q for related discussions on our adoption of the recent accounting pronouncement. Additionally, we continue to evaluate accounting standards that were recently issued but not yet adopted, as applicable.

Liquidity and Capital Resources

Liquidity

As of September 30, 2021, we had approximately $143.1 million in cash, cash equivalents and short-term investments, as compared to approximately $57.3 million as of December 31, 2020. The increase of approximately $85.8 million was primarily attributable to the upfront cash payment of $125.0 million from Lilly, partially offset by cash used in our other operating activities. As of September 30, 2021 and December 31, 2020, we maintained investment portfolios primarily in money market funds, U.S. treasury bills, government-sponsored enterprise securities, and corporate bonds and commercial paper. Cash in excess of immediate requirements is invested with regard to liquidity and capital preservation. We view our investments portfolio as available-for-sale and are available for use in current operations. Wherever possible, we seek to minimize the potential effects of concentration and degrees of risk. We continue to monitor the impact of the changes in the conditions of the credit and financial markets to our investment portfolio and assess if future changes in our investment strategy are necessary.

Following summarizes our cash flow activity for the periods presented:

	Nine Months Ended September 30,	
	2021	2020
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ 24,964	$ (36,613)
Investing activities	(86,524)	38,755
Financing activities	61,590	11,904
Net increase in cash and cash equivalents	$ 30	$ 14,046

Net cash provided by operating activities was $25.0 million for the nine months ended September 30, 2021, compared to net cash used in operating activities of $36.6 million for the nine months ended September 30, 2020. Net cash provided by operating activities for the nine months ended September 30, 2021 was primarily due to the cash received from Lilly for the portion allocated as net transaction price of $67.1 million, proceeds from sales of TAVALISSE, cash received from the awards granted by the U.S. Department of Defense of $9.5 million, cash received

related to a non-exclusive license agreement with an unrelated third party of $4.0 million, and cash received from Grifols of $1.0 million for a delivery of drug supply for its commercialization. These increases were partially offset by payments of our research and development programs and other operating expenses. Net cash used in operating activities for the nine months ended September 30, 2020 was primarily related to cash payments for our research and development programs and other operating expenses, partially offset by the $20.0 million payment received from Grifols and proceeds from sale of TAVALISSE.

Net cash used in investing activities was $86.5 million for the nine months ended September 30, 2021, compared to net cash provided by investing activities of $38.8 million for the nine months ended September 30, 2020. Net cash used in investing activities during the nine months ended September 30, 2021 was due to net purchases of short-term investments of $85.9 million and capital expenditures of $648,000. Net cash provided by investing activities during the nine months ended September 30, 2020 was due to net maturities of short-term investments of $39.5 million, partially offset by capital expenditures of $758,000.

Net cash provided by financing activities was approximately $61.6 million for the nine months ended September 30, 2021, compared to approximately $11.9 million for the nine months ended September 30, 2020. Net cash provided by financing activities for the nine months ended September 30, 2021 was primarily due to the cash received from Lilly for the portion allocated as financing component amounting to $57.9 million, and proceeds from exercise of stock options and participation in our Employee Stock Purchase Plan (Purchase Plan) amounting to $3.7 million. Net cash provided by financing activities for the nine months ended September 30, 2020 was related to the net proceeds from funding of Tranche 2 from our term loan credit facility with MidCap of $10.0 million and exercise of stock options and participation in the Purchase Plan of $1.9 million.

We believe that our existing capital resources will be sufficient to support our current and projected funding requirements, including the continued commercialization of TAVALISSE, through at least the next 12 months from the Form 10-Q filing date. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with commercializing a product, the development of our product candidates and other research and development activities, we are unable to estimate with certainty our future product revenues, our revenues from our current and future collaborative partners, the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials and other research and development activities.

Capital Resources

Since inception, we have financed our operations primarily through sales of equity securities, contract payments under our collaboration agreements and from sales of TAVALISSE beginning in May 2018. We have consumed substantial amounts of capital resources to date as we continue our research and development activities, including preclinical studies and clinical trials and our ongoing commercial launch of TAVALISSE.

In addition to the upfront cash payment we received from Lilly under the Lilly Agreement, we may also be eligible for potential development, regulatory, and commercial milestone payments totaling up to an additional $835.0 million, as well as tiered royalties on net sales of non-CNS and CNS disease products up to low-double digits that will vary depending upon our clinical development investment. Further, under our other sponsored research and license agreements with Griffols, Kissei, Medison, AZ, BerGenBio and Daiichi, we may be entitled to receive upfront cash payments, payments contingent upon specified events achieved by such partners. Total future contingent payments to us under such agreements (excluding Lilly) could exceed $500.0 million if all potential product candidates achieved all of the payment triggering events under such agreements (based on a single product candidate under each agreement). See further discussions of our Sponsored Research and License Agreements and Government Contract in Note 8 to our “Notes to Condensed Financial Statements” contained in Part I, Item 1 of this Quarterly Report on Form 10-Q.

In January 2021, we were awarded $16.5 million by the U.S. Department of Defense to support our ongoing Phase 3 clinical trial to evaluate the safety and efficacy of fostamatinib in hospitalized COVID-19 patients. Under the agreement with the U.S. Department of Defense, we are entitled to receive such award based on the agreed-upon payment schedule, subject to submission of proper documentation as evidence of completion of certain clinical trial events or milestones as specified in the agreement, and approval by the U.S. Department of Defense that such events or milestones have been met. During the three and nine months ended September 30, 2021, we recognized income from the awards from the U.S. Department of Defense of $1.0 million and $9.5 million, respectively. We expect to receive the remaining awards of $7.0 million throughout the period of which we conduct our clinical trial, subject to us meeting certain clinical trial events or milestones and approval by the U.S. Department of Defense as specified in the agreement.

In August 2020, we entered into an Open Market Sale Agreemen.SM with Jefferies LLC, as a sole agent, pursuant to which we may sell from time to time, through Jefferies, shares of our common stock in sales deemed to be "at-the-market offerings" as defined in Rule 415 under the Securities Act, subject to conditions specified in the Open Market Sale Agreement, including maintaining an effective registration statement covering the sale of shares under the Open Market Sale Agreement. In April 2021, the registration statement registering the sale of shares under the Open Market Sale Agreement expired. From the time of implementation of the Open Market Sale Agreement through expiration of the registration statement, no sales of shares occurred. A new automatic shelf registration statement was filed on August 3, 2021 to register the sale of up to a maximum aggregate offering price of $100.0 million of shares of our common stock that may be issued and sold from time to time under the Open Market Sale Agreement.

As of September 30, 2021, we have principal term loan outstanding with MidCap amounting to $20.0 million, pursuant to the Credit and Security Agreement (Credit Agreement) we entered in September 2019. The Credit Agreement provides for $60.0 million term loan credit facility. To date, the credit facility provides us with access for an additional $40.0 million term loan subject to the achievement of certain customary conditions.

We have a sublease agreement originally entered in December 2014, and subsequently amended in February 2017 and July 2017, with an unrelated third party to occupy a portion of our research and office space which expire in January 2023. As of September 30, 2021, we expect to receive approximately $6.2 million in future sublease income (excluding our subtenant's share of facility's operating expenses) through January 2023.

Our operations will require significant additional funding for the foreseeable future. Unless and until we are able to generate a sufficient amount of product, royalty or milestone revenue, we expect to opportunistically finance future cash needs through public and/or private offerings of equity securities, debt financings and/or collaboration and licensing arrangements, and to a much lesser extent through the proceeds from exercise of stock options and interest income earned on the investment of our excess cash balances and short-term investments. However, the COVID-19 pandemic continues to rapidly evolve and has already resulted in a significant disruption of global financial markets. Our ability to raise additional capital may be adversely impacted by potential worsening of global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the U.S. and worldwide resulting from the pandemic. If the disruption persists and deepens, we could experience an inability to access additional capital, which could in the future negatively affect our capacity for certain corporate development transactions or our ability to make important, opportunistic investments. In addition, any additional capital we raise by issuing equity securities, our stockholders could at that time experience substantial dilution. Our current credit facility with MidCap and any debt financing that we are able to obtain in the future may involve operating covenants that may restrict our business. To the extent that we raise additional funds through collaboration and licensing arrangements, we may be required to relinquish some of our rights to our technologies or product candidates or grant licenses on terms that are not favorable to us.

Our future funding requirements will depend upon many factors, including, but not limited to:

- the ongoing costs to commercialize TAVALISSE for the treatment of ITP in the U.S., or any other future product candidates, if any such candidate receives regulatory approval for commercial sale;
- the progress and success of our clinical trials and preclinical activities (including studies and manufacture of materials) of our product candidates conducted by us;
- our ability to meet operating covenants under our current and future credit facilities, if any;
- our ability to enter into partnering opportunities across our pipeline within and outside the U.S.;

- the costs and timing of regulatory filings and approvals by us and our collaborators;
- the progress of research and development programs carried out by us and our collaborative partners;
- any changes in the breadth of our research and development programs;
- the ability to achieve the events identified in our collaborative agreements that may trigger payments to us from our collaboration partners;
- our ability to acquire or license other technologies or compounds that we may seek to pursue;
- our ability to manage our growth;
- competing technological and market developments;
- the costs and timing of obtaining, enforcing and defending our patent and other intellectual property rights; and
- expenses associated with any unforeseen litigation, including any arbitration and securities class action lawsuits.

Insufficient funds may require us to delay, scale back or eliminate some or all of our commercial efforts and/or research or development programs, to lose rights under existing licenses or to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose or may adversely affect our ability to operate as a going concern.

Material Cash Requirements

We conduct our commercial activities and research and development programs internally and through third parties that include, among others, arrangements with vendors, consultants, contract research organizations (CRO) and universities. We have contractual arrangements with these parties, however our contracts with them are cancelable generally on reasonable notice within one year and our obligations under these contracts are primarily based on services performed. We do not have any purchase commitments under any collaboration arrangements.

We have agreements with certain clinical research organizations to conduct our clinical trials and with third parties relative to our commercialization of TAVALISSE. The timing of payments for any amounts owed under the respective agreements will depend on various factors including, but not limited to, patient enrollment and other progress of the clinical trial and various activities related to commercial launch. We expect we will continue to enter into contracts in the normal course of business with various third parties who support our clinical trials, support our preclinical research studies, and provide other services related to our operating purposes as well as our commercial launch of TAVALISSE. We can terminate these agreements at any time, and if terminated, we would not be liable for the full amount of the respective agreements. Instead, we will be liable for services provided through the termination date plus certain cancellation charges, if any, as defined in each of the respective agreements. In addition, these agreements may, from time to time, be subjected to amendments as a result of any change orders executed by the parties.

As discussed in detail in Note 8 of Notes to Condensed Financial Statement, pursuant to our global exclusive license agreement and strategic collaboration agreement with Lilly, we are responsible for funding the development costs for R552 in the U.S., Europe, and Japan, up to $65.0 million through April 1, 2024. We have the right to opt- out of co-funding of development costs at two different specified times. If we decide not to exercise our opt-out rights, we will be required to share in global development costs up to certain amounts at a specified cap, as set forth in the agreement.

As of September 30, 2021, we do not have other material contractual commitments with respect to the arrangements discussed above nor we had off-balance sheet arrangements, but we had the following contractual commitments related to our facilities lease and credit facility:

	Payment Due By Period				
	Total	Less than 1 Year	1 - 3 Years	3 - 5 Years	More than 5 Years
			(in thousands)		
Facilities lease (1)	$ 13,891	$ 10,384	$ 3,507	$ —	$ —
Credit facility with MidCap (2)	22,915	1,430	21,485	—	—
Total	$ 36,806	$ 11,814	$ 24,992	$ —	$ —

(1) The facilities lease obligations do not include the sublease income as discussed above.

(2) Under our Credit Agreement with MidCap, we are obligated to make interest payments at an annual rate of one-month LIBOR plus 5.65%, originally for the first 24 months and the interest plus principal amortization for the next 36 months. Our Credit Agreement provides us an option to extend the interest-only period to 36 months and again to 48 months upon the satisfaction of certain conditions set forth in the Credit Agreement. In June 2021, we satisfied the conditions under the Credit Agreement which effectively extended the interest-only period to 36 months or through October 1, 2022. We are also obligated to pay administrative fees annually and a final fee upon final payment.

We are also subject to claims related to the patent protection of certain of our technologies, as well as purported securities class action lawsuit, other litigations, and other contractual agreements. We are required to assess the likelihood of any adverse judgments or outcomes to these matters as well as potential ranges of probable losses. A determination of the amount of reserves required, if any, for these contingencies is made after careful analysis of each individual matter.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures. Based on the evaluation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), our chief executive officer (who serves as our principal executive officer) and our chief financial officer (who serves as our principal financial officer) have concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective.

Changes in Internal Controls. There were no changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the controls are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met and, as set forth above, our chief executive officer and chief financial officer have concluded, based on their evaluation as of the end of the period covered by this report, that our disclosure controls and procedures were sufficiently effective to provide reasonable assurance that the objectives of our disclosure control system were met.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

In evaluating our business, you should carefully consider the following risks, as well as the other information contained in this Quarterly Report on Form 10-Q. These risk factors could cause our actual results to differ materially from those contained in forward-looking statements we have made in this Quarterly Report on Form 10-Q and those we may make from time to time. If any of the following risks actually occurs, our business, financial condition and operating results could be harmed. The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties not presently known to us, or that we currently see as immaterial, may also harm our business.

We have marked with an asterisk (*) those risk factors below that reflect a substantive change from the risk factors included in our Annual Report on Form 10-K filed with the SEC on March 2, 2021.

Risk Factor Summary

- Our prospects are highly dependent on our first commercial product, TAVALISSE (fostamatinib disodium hexahydrate). To the extent that the commercial success of TAVALISSE or fostamatinib in the United States and respective territories outside of the United States is diminished or is not commercially successful, our business, financial condition and results of operations may be adversely affected, and the price of our common stock may decline.

- Our business is currently adversely affected and could be materially and adversely affected in the future by the evolving effects of the COVID-19 pandemic as a result of the current and potential future impacts on our sales force and commercialization efforts, supply chain, regulatory, clinical development and corporate development activities and other business operations, in addition to the impact of a global economic slowdown.

- Even if we, or any of our collaborative partners, are able to continue to commercialize TAVALISSE or any product candidate that we, or they, develop, the product may become subject to unfavorable pricing regulations, third-party payor reimbursement practices or labeling restrictions, all of which may vary from country to country and any of which could harm our business.

- If we are unable to successfully market and distribute TAVALISSE and retain experienced sales force, our business will be substantially harmed.

- We are subject to stringent and evolving privacy and information security laws, regulations, rules, policies and contractual obligations, and changes in such laws, regulations, rules, policies, contractual obligations and our actual or perceived failure to comply with such requirements could subject us to significant investigations, fines, penalties, and claims, any of which may have a material adverse effect on our business, financial condition, results of operations or prospects.

- If manufacturers obtain approval for generic versions of TAVALISSE, or of products with which we compete, our business may be harmed.

- Unforeseen safety issues could emerge with TAVALISSE that could require us to change the prescribing information to add warnings, limit use of the product, and/or result in litigation. Any of these events could have a negative impact on our business.

- We rely and may continue to rely on two distribution facilities for the sale of TAVALISSE and potential sale of any of our product candidates.

- We may not be able to obtain Emergency Use Authorization (EUA) for fostamatinib for the treatment of hospitalized patients with COVID-19, and, even if we do, absent supplemental NDA approval for that indication, such EUA would be revoked when the COVID-19 emergency terminates.

- We lack the capability to manufacture compounds for clinical development and we intend to rely on third parties for commercial supply, manufacturing and distribution if any of our product candidates which receive regulatory approval and we may be unable to obtain required material or product in a timely manner, at an acceptable cost or at a quality level required to receive regulatory approval.

- We might not be able to successfully develop or commercialize our product candidates if problems arise in the clinical testing and approval process. There is a high risk that drug discovery and development efforts might not generate successful product candidates.

- Any product for which we have obtained regulatory approval, or for which we obtain approval in the future, is subject to, or will be subject to, extensive ongoing regulatory requirements by the FDA, EMA and other comparable regulatory authorities, and if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, we may be subject to penalties, we will be unable to generate revenue from the sale of such products, our potential for generating positive cash flow will be diminished, and the capital necessary to fund our operations will be increased.

- If our corporate collaborations or license agreements are unsuccessful, or if we fail to form new corporate collaborations or license agreements, our research and development efforts could be delayed.

- Our success is dependent on intellectual property rights held by us and third parties, and our interest in such rights is complex and uncertain.

- If a dispute arises regarding the infringement or misappropriation of the proprietary rights of others, such dispute could be costly and result in delays in our research and development activities and partnering.

- If our competitors develop technologies that are more effective than ours, our commercial opportunity will be reduced or eliminated.

- If product liability lawsuits are successfully brought against us, we may incur substantial liabilities and may be required to limit commercialization of our products.

Risks Related to Our Business and Our Industry

If the market opportunities for TAVALISSE and product candidates are smaller than we believe they are, our revenues may be adversely affected, and our business may suffer.

Certain of the diseases that TAVALISSE and our other product candidates being developed to address are in underserved and underdiagnosed populations. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who will seek treatment utilizing our products or product candidates, may not be accurate. If our estimates of the prevalence or number of patients potentially on therapy prove to be inaccurate, the market opportunities for fostamatinib and our other product candidates may be smaller than what we believe they are, our prospects for generating expected revenue may be adversely affected and our business may suffer. For example, complications due to COVID-19 may be prevented or well-addressed by others entering the market with vaccines or therapeutics to prevent or treat COVID-19, thereby affecting projections of the market for our product candidate negatively, and adversely affecting our business.

We may need to continue to increase the size of our organization and we may encounter difficulties with managing our growth, which could adversely affect our business and results of operations.*

Although we have recently substantially increased the size of our organization, we may need to add additional qualified personnel and resources to support our commercial sales force. Our current infrastructure may be inadequate to support our development and commercialization efforts and expected growth. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees, and may take time away from running other aspects of our business, including commercialization of TAVALISSE and development of our other product candidates.

Our future financial performance and our ability to sustain successful commercialization of TAVALISSE and our ability to commercialize other product candidates that may receive regulatory approval will depend, in part, on our ability to manage any future growth effectively. In particular, as we continue to commercialize TAVALISSE, we will need to support the training and ongoing activities of our sales force and will likely need to continue to expand the size of our employee base for managerial, operational, financial and other resources. To that end, we must be able to successfully:

- manage our development efforts effectively;
- integrate additional management, administrative and manufacturing personnel;
- further develop our marketing and sales organization; and
- maintain sufficient administrative, accounting and management information systems and controls.

We may not be able to accomplish these tasks or successfully manage our operations and, accordingly, may not achieve our research, development, and commercialization goals. Our failure to accomplish any of these goals, including as a result of business or other interruptions resulting from the ongoing COVID-19 pandemic, could adversely affect our business and operations.

There is a high risk that drug discovery and development efforts might not generate successful product candidates.*

At the present time, a significant portion of our operations are focused on various stages of drug identification and development. We currently have various product candidates in the clinical testing stage. In our industry, it is statistically unlikely that the limited number of compounds that we have identified as potential product candidates will actually lead to successful product development efforts. We have invested a significant portion of our efforts and financial resources into the development of fostamatinib. Our ability to generate product revenue, which will not occur until after regulatory approval, if ever, will depend on the successful development, regulatory approval and eventual commercialization of one of our product candidates.

Our compounds in clinical trials and our future leads for potential drug compounds are subject to the risks and failures inherent in the development of pharmaceutical products. These risks include, but are not limited to, the inherent difficulty in selecting the right drug and drug target and avoiding unwanted side effects, as well as unanticipated problems relating to product development, testing, enrollment, obtaining regulatory approvals, maintaining regulatory compliance, manufacturing, competition and costs and expenses that may exceed current estimates. In future clinical trials, we or our partners may discover additional side effects and/or higher frequency of side effects than those observed in previously completed clinical trials. The results of preliminary and mid-stage clinical trials do not necessarily predict clinical or commercial success, and larger later-stage clinical trials may fail to confirm the results observed in the previous clinical trials. Similarly, a clinical trial may show that a product candidate is safe and effective for certain patient populations in a particular indication, but other clinical trials may fail to confirm those results in a subset of that population or in a different patient population, which may limit the potential market for that product candidate. With respect to our own compounds in development, we have established anticipated timelines with respect to the initiation of clinical trials based on existing knowledge of the compounds. However, we cannot provide assurance that we will meet any of these timelines for clinical development. Additionally, the initial results of a completed earlier clinical trial of a product candidate do not necessarily predict final results and the results may not be repeated in later clinical trials.

Because of the uncertainty of whether the accumulated preclinical evidence (PK, pharmacodynamic, safety and/or other factors) or early clinical results will be observed in later clinical trials, we can make no assurances regarding the likely results from our future clinical trials or the impact of those results on our business. For example, if our Phase 3 clinical trial in wAIHA or Phase 3 clinical trial to further evaluate fostamatinib in hospitalized patients with COVID-19, or any of our clinical trials fail to meet the primary efficacy endpoints, the commercial prospects of our business may be harmed, our ability to generate product revenues may be delayed or eliminated or we may be forced to undertake other strategic alternatives that are in our shareholders' best interests, including cost reduction measures. If we are unable to obtain adequate financing or engage in a strategic transaction on commercially reasonable terms or at all, we may be required to implement further cost reduction strategies which could significantly impact activities related to our commercial efforts and/or research and development of our future product candidates, and could significantly harm our business, financial condition and results of operations. In addition, these cost reduction strategies could cause us to further curtail our operations or take other actions that would adversely impact our shareholders.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and other federal and state healthcare laws, and the failure to comply with such laws could result in substantial penalties. Our employees, independent contractors, consultants, principal investigators, CROs, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payers and customers, may expose us to broadly applicable federal, state and foreign fraud and abuse and other healthcare laws and regulations including anti-kickback and false claims laws, data privacy and security laws, and transparency reporting laws. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute any product for which we have obtained regulatory approval, or for which we obtain regulatory approval in the future. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws and regulations intended to prevent fraud, misconduct, bribery kickbacks, self-dealing and other abusive or inappropriate practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, including promoting off-label uses of our products, commission compensation, certain customer incentive programs, certain patient support offerings, and other business arrangements generally. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of patient recruitment for clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. See "Business – Government Regulation – Healthcare and Privacy Law and Regulation" in Part I, Item 1 of our Annual Report on Form 10-K filed on March 2, 2021 for more information on the healthcare laws and regulations that may affect our ability to operate.

We are also exposed to the risk of fraud, misconduct or other illegal activity by our employees, independent contractors, consultants, principal investigators, CROs, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to: comply with the laws of the FDA and other similar foreign regulatory bodies; provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies; comply with manufacturing standards we have established; comply with federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and similar foreign fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities to us. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations.

We are also subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. Efforts to ensure that our business arrangements will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, disgorgement, monetary fines, imprisonment, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We are subject to stringent and evolving privacy and information security laws, regulations, rules, policies, and contractual obligations, and changes in such laws, regulations, rules, policies, contractual obligations and our actual or perceived failure to comply with such requirements could subject us to significant investigations, fines, penalties and claims, any of which may have a material adverse effect on our business, financial condition, results of operations or prospects.*

We are subject to, or affected by, various federal, state and foreign laws, rules, directives, and regulations, as well as regulatory guidance, policies and contractual obligations relating to privacy and information security, governing

the collection, access, acquisition, use, disclosure, processing, modification, retention, storage, transfer, destruction, protection, and security (collectively, "processing") of personal information and other sensitive information about individuals. The global privacy and information security landscape is evolving rapidly, and implementation standards and enforcement practices are likely to continue to develop for the foreseeable future and may result in conflicting or inconsistent compliance obligations. Legislators and regulators are increasingly adopting or revising privacy and information security laws, rules, directives, and regulations that may create uncertainty in our business, affect our or our collaborators', service providers' and contractors' ability to operate in certain jurisdictions or to process personal information, transfer data internationally, necessitate the acceptance of more onerous obligations in our contracts, result in enforcement actions, litigation or other liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us or our collaborators, service providers and contractors to comply with federal, state or foreign laws or regulations, our internal policies and procedures or our contracts governing the processing of personal information could result in negative publicity, diversion of management time and effort and proceedings against us by governmental entities or others. In many jurisdictions, enforcement actions, litigation, and other consequences for noncompliance with privacy and information security laws and regulations are rising. Compliance with applicable privacy and information security laws and regulations, as well as regulatory guidance, policies and contractual obligations, is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms to ensure compliance with the new privacy and information security requirements. If we fail to comply with any such obligations, we may face significant investigations, fines, penalties and claims that could materially and adversely affect our business, financial condition, results of operations, ability to process personal information, and could reduce income from certain business initiatives.

In the U.S., these include various federal, state, and local statutes, rules, and regulations relating to privacy and data security. The Federal Trade Commission ("FTC") has authority under Section 5 of the FTC Act to regulate unfair, deceptive, or abusive acts or practices, and has used this authority to initiate enforcement actions against companies that implement inadequate controls around privacy and information security in violation of their externally facing policies. The U.S. federal government has also enacted statutes to address privacy and information security issues impacting particular industries or activities, including the following laws and regulations: the Electronic Communications Privacy Act, the Computer Fraud and Abuse Act, the Health Insurance Portability and Accountability Act, the Health Information Technology for Economic and Clinical Health Act, the Telephone Consumer Protection Act, the CAN-SPAM Act, and other laws and regulations. In addition, state legislatures have enacted statutes to address privacy and information security issues, including the California Consumer Privacy Act of 2018, or the CCPA, and similar state laws such as Virginia's Consumer Data Protection Act and the Colorado Privacy Act. For example, the CCPA establishes a privacy framework applicable to for-profit entities that are doing business in California, including an expansive definition of personal information and data privacy rights for California residents. The CCPA, among other things, authorizes the imposition of potentially severe statutory damages and created a private right of action for data security breaches. The CCPA also requires businesses subject to the law to provide new disclosures to California residents and to provide them with expanded rights with respect to their personal information, including the right to opt- out of the sale of such information. Although there are limited exemptions for clinical trial and other research-related data under the CCPA, the CCPA and other similar laws could impact our business depending on how the CCPA will be interpreted by the new California Privacy Protection Agency. As we expand our operations, the CCPA may increase our compliance costs and potential liability. In addition, in November 2020, California voters approved the California Privacy Rights Act of 2020, or CPRA, that goes into effect on January 1, 2023. The CPRA will, among other things, give California residents the ability to limit the use of their sensitive information, opt- out of certain types of profiling and automated processing activities, provide for penalties for CPRA violations concerning California residents under the age of 16, and establish a new California Privacy Protection Agency to implement and enforce the law. Additionally, Colorado and Virginia both signed privacy legislation earlier this year, each of which go into effect in 2023, and multiple other states as well as the federal government are considering enacting similar legislation. Many states also have in place data security laws requiring companies to maintain certain safeguards with respect to the processing of personal information, and all states require companies to notify individuals or government regulators in the event of a data breach impacting such information. New privacy laws add additional complexity, requirements, restrictions and potential legal risk. Accordingly, compliance programs may require additional investment in resources, and could impact availability of previously useful data.

Internationally, our operations abroad may also be subject to increased scrutiny or attention from foreign data protection authorities. For example, our clinical trial programs and research collaborations outside the United States may implicate foreign data protection laws, including in the European Economic Area, Switzerland, and/or the UK (collectively, "Europe"). Many jurisdictions have established or are in the process of establishing privacy and data security legal frameworks with which we, our collaborators, service providers, including our CROs, and contractors must comply. For example, European data protection laws, including, without limitation, the EU General Data Protection Regulation, or the EU GDPR, impose strict requirements for processing personal information (i.e., data which identifies an individual or from which an individual is identifiable), including clinical trial data and grant individuals various data protection rights (e.g., the right to erasure of personal information). In turn, the EU GDPR and similar laws increase our obligations with respect to clinical trials conducted in Europe by expanding the definition of personal information to include also coded data and requiring (i) changes to informed consent practices and more detailed notices for clinical trial participants and investigators, (ii) us to consider data protection as any new products or services are developed and to limit the amount of personal information processed; and (iii) us to implement appropriate technical and organizational measures to safeguard personal information and to report certain personal data breaches to the supervisory authority without undue delay (for the EU GDPR no later than 72 hours where feasible). In the event of non-compliance, the EU GDPR provides for robust regulatory enforcement and fines of up to €20 million or 4% of the annual global revenue, whichever is greater. In addition, the EU GDPR confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the EU GDPR.

European data protection laws, including the EU GDPR, generally also prohibits the transfer of personal information from Europe to the United States and most other countries that are not recognized as having "adequate" data protection laws by the European Commission unless the parties to the transfer have implemented specific safeguards to protect the transferred personal information. One of the primary safeguards allowing U.S. companies to import personal information from Europe has been certification to the EU-U.S. Privacy Shield and Swiss-U.S. Privacy Shield frameworks administered by the U.S. Department of Commerce. However, the Court of Justice of the European Union (CJEU) issued a decision in July 2020 invalidating the EU-U.S. Privacy Shield framework (*Schrems II*) and imposing further restrictions on the use of standard contractual clauses (SCCs) including, a requirement for companies to carry out a transfer privacy impact assessment, which among other things, assesses laws governing access to personal information in the recipient country and considers whether supplementary measures that provide privacy protections additional to those provided under the SCCs will need to be implemented to ensure an essentially equivalent level of data protection to that afforded in Europe. Following that decision, the Swiss Federal Data Protection and Information Commissioner (FDPIC) took a similar view and considered that data transfers based on the Swiss-U.S. Privacy Shield framework are no longer lawful (despite the fact that *Schrems II* is not directly applicable in Switzerland (unless the Swiss based company is subject to the EU GDPR) and the Swiss-U.S. Privacy Shield has not been officially invalidated). Further, the European Commission recently published new EU SCCs, which place onerous obligations on the contracting parties. At present, there are few, if any, viable alternatives to the SCCs. As such, any transfers by us or our third-party vendors, collaborators of others of personal information from Europe to the United States or elsewhere may not comply with European data protection laws; may increase our exposure to European data protection laws' heightened sanctions for cross-border data transfer restrictions; may restrict our clinical trial activities in Europe; and limit our ability to collaborate with CROs, service providers, contractors and other companies subject to European data protection laws. Loss of our ability to transfer personal information from Europe may also require us to increase our data processing capabilities in those jurisdictions at significant expense.

Following the UK's departure from the EU (Brexit), the EU GDPR's data protection obligations continue to apply to the UK in substantially unvaried form under the so-called "UK GDPR" (i.e., the EU GDPR as it continues to form part of law in the UK by virtue of section 3 of the European Union (Withdrawal) Act 2018, as amended (including by the various Data Protection, Privacy and Electronic Communications (Amendments etc) (EU Exit) Regulations)). The UK GDPR exists alongside the UK Data Protection Act 2018 that implements certain derogations in the UK GDPR into UK law. Under the UK GDPR, companies not established in the UK but who process personal information in relation to the offering of goods or services to individuals in the UK, or to monitor their behavior will be subject to the UK GDPR – the requirements of which are (at this time) largely aligned with those under the EU GDPR and as such, may lead to similar compliance and operational costs with potential fines of up to £17.5 million or 4% of global turnover. As a result, we are potentially exposed to two parallel data protection regimes, each of which authorizes fines and the potential for divergent enforcement actions. It should also be noted that the new EU SCCs do not automatically apply in the UK since Brexit, and the UK Government has not yet formally acknowledged the new EU SCCs, *i.e.*, as a valid data transfer

mechanism under the UK GDPR. Indeed, on August 11, 2021, the UK Information Commissioner's Office (ICO) launched a public consultation on its draft international data transfer agreement and guidance. This included the publication of a draft UK addendum that can be used with the new EU SCCs – however this is unlikely to be finalized before the end of 2021 and as such, for the time being transfers from the UK to a third country should continue to be made in reliance on the "old" SCCs.

Additionally, other countries outside of Europe have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, and strict requirements and limitations for processing personal information, which could increase the cost and complexity of delivering our services and operating our business. For example, Brazil enacted the General Data Protection Law, New Zealand enacted the New Zealand Privacy Act, China released its Personal Information Protection Law, which went into effect November 1, 2021, and Canada introduced the Digital Charter Implementation Act. As with the EU GDPR, these laws are broad and may increase our compliance burdens, including by mandating potentially burdensome documentation requirements and granting certain rights to individuals to control how we collect, use, disclose, retain, and process personal information about them.

We publish privacy policies and other documentation regarding our collection, processing, use and disclosure of personal information and/or other confidential information. Although we endeavor to comply with our published policies and other documentation, we may at times fail to do so or may be perceived to have failed to do so. Moreover, despite our efforts, we may not be successful in achieving compliance if our employees, collaborators, contractors, service providers or vendors fail to act in accordance with our published policies and documentation. Such failures can subject us to potential foreign, local, state and federal action if they are found to be deceptive, unfair, or misrepresentative of our actual practices. Moreover, trial participants or research subjects about whom we or our partners obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information, or exercise rights to do so under applicable privacy legislation. Claims that we have violated individuals' privacy rights or failed to comply with data protection laws or applicable privacy policies and documentation, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

In addition to data privacy requirements, many jurisdictions have mandatory clinical trial information obligations on sponsors. In the EU this is under the Transparency Regulation No 1049/ 2001, EMA Policy 0043, EMA Policy 0070, as well as the Clinical Trials Regulation No 536/2014, all of which impose on sponsors the obligation to make publicly available certain information stemming from clinical studies. In the EU, the transparency framework provides for a wide right for (EU-based at the moment) interested parties to submit an access to documents request to the EMA for information included in the marketing authorization application dossier for approved medicinal products. Only very limited information is exempted from disclosure, i.e. commercially confidential information (which is construed increasingly narrowly) and protected personal data. It is possible for competitors to access and use this data in their own research and development programs anywhere in the world, once this data is in the public domain.

Enhanced governmental and public scrutiny over, or investigations or litigation involving, pharmaceutical manufacturer donations to patient assistance programs may require us to modify our programs and could negatively impact our business practices, harm our reputation, divert the attention of management and increase our expenses.*

To help patients afford our products, we have a patient assistance program that helps financially needy patients. This type of program has become the subject of scrutiny. Some pharmaceutical manufacturers were named in class action lawsuits challenging the legality of their patient assistance programs under a variety of federal and state laws. Our patient assistance program could become the target of similar litigation. In addition, certain state and federal enforcement authorities and members of Congress have initiated inquiries about manufacturer-sponsored patient assistance programs, including, for example, manufacturer-sponsored patient assistance programs, co-pay assistance programs, and manufacturer contributions to independent charitable patient assistance programs. Some state legislatures have also been considering proposals that would restrict or ban co-pay coupons.

If we are deemed not to have complied with laws or regulations in the operation of, or our interactions with, these programs, we could be subject to damages, fines, penalties or other criminal, civil or administrative sanctions or enforcement actions. Further, numerous organizations, including pharmaceutical manufacturers, have been subject to ongoing litigation, enforcement activities and settlements related to their patient assistance programs and support, and certain of these organizations have entered into, or have otherwise agreed to, significant civil settlements with applicable

enforcement authorities. It is possible that future legislation may propose establishing requirements with respect to these programs and/or support that affect pharmaceutical manufacturers. We cannot ensure that our compliance controls, policies and procedures will be sufficient to protect against acts of our employees, business partners or vendors that may violate the laws or regulations of the jurisdictions in which we operate. A government investigation could negatively impact our business practices, harm our reputation, divert the attention of management and increase our expenses.

If manufacturers obtain approval for generic versions of TAVALISSE, or of products with which we compete, our business may be harmed.

Under the U.S. Food, Drug and Cosmetic Act (FDCA), the FDA can approve an abbreviated new drug application (ANDA) for a generic version of a branded drug without the ANDA applicant undertaking the clinical testing necessary to obtain approval to market a new drug. Generally, in place of such clinical studies, an ANDA applicant usually needs only to submit data demonstrating that its product has the same active ingredient(s), strength, dosage form, route of administration and that it is bioequivalent to the branded product. In September 2019, the FDA published product-specific bioequivalence guidance on fostamatinib disodium to let potential ANDA applicants understand the data FDA would expect to see for approval of a generic version of TAVALISSE.

The FDCA requires that an applicant for approval of a generic form of a branded drug certify either that its generic product does not infringe any of the patents listed by the owner of the branded drug in the Orange Book or that those patents are not enforceable. This process is known as a paragraph IV challenge. Upon notice of a paragraph IV challenge, a patent owner has 45 days to bring a patent infringement suit in federal district court against the company seeking ANDA approval of a product covered by one of the owner's patents. If this type of suit is commenced, the FDCA provides a 30-month stay on the FDA's approval of the competitor's application. If the litigation is resolved in favor of the ANDA applicant or the challenged patent expires during the 30-month stay period, the stay is lifted, and the FDA may thereafter approve the application based on the standards for approval of ANDAs. Once an ANDA is approved by the FDA, the generic manufacturer may market and sell the generic form of the branded drug in competition with the branded medicine.

The ANDA process can result in generic competition if the patents at issue are not upheld or if the generic competitor is found not to infringe the owner's patents. If this were to occur with respect to TAVALISSE or products with which it competes, our business would be harmed. We have a number of patents listed in the Orange Book, the last of which is expected to expire in July 2032.

Unforeseen safety issues could emerge with TAVALISSE that could require us to change the prescribing information to add warnings, limit use of the product, and/or result in litigation. Any of these events could have a negative impact on our business.

Discovery of unforeseen safety problems or increased focus on a known problem could impact our ability to commercialize TAVALISSE and could result in restrictions on its permissible uses, including withdrawal of the medicine from the market.

If we or others identify additional undesirable side effects caused by TAVALISSE after approval:

- regulatory authorities may require the addition of labeling statements, specific warnings, contraindications, or field alerts to physicians and pharmacies;
- regulatory authorities may withdraw their approval of the product and require us to take our approved drugs off the market;
- we may be required to change the way the product is administered, conduct additional clinical trials, change the labeling of the product, or implement a Risk Evaluation and Mitigation Strategy, or REMS;
- we may have limitations on how we promote our drugs;
- third-party payers may limit coverage or reimbursement for TAVALISSE;

- sales of TAVALISSE may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of TAVALISSE and could substantially increase our operating costs and expenses, which in turn could delay or prevent us from generating significant revenue from sale of TAVALISSE.

If a safety issue emerges post-approval, we may become subject to costly product liability litigation by our customers, their patients or payers. Product liability claims could divert management's attention from our core business, be expensive to defend, and result in sizable damage awards against us that may not be covered by insurance. If we cannot successfully defend ourselves against claims that TAVALISSE caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- the inability to commercialize any products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of patients from clinical studies or cancellation of studies;
- significant costs to defend the related litigation;
- substantial monetary awards to patients; and
- loss of revenue.

We currently hold $10.0 million in product liability insurance coverage, which may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to obtain insurance coverage at a reasonable cost or in amounts adequate to satisfy any liability or associated costs that may arise in the future. These events could harm our business and results of operations and cause our stock price to decline.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in the United States, we could be subject to additional reimbursement requirements, fines, sanctions and exposure under other laws which could have an adverse effect on our business, results of operations and financial condition.

We participate in the Medicaid Drug Rebate Program, as administered by the CMS, and other federal and state government pricing programs in the United States, and we may participate in additional government pricing programs in the future. These programs generally require us to pay rebates or otherwise provide discounts to government payers in connection with drugs that are dispensed to beneficiaries/recipients of these programs. In some cases, such as with the Medicaid Drug Rebate Program, the rebates are based on pricing that we report on a monthly and quarterly basis to the government agencies that administer the programs. Pricing requirements and rebate/discount calculations are complex, vary among products and programs, and are often subject to interpretation by governmental or regulatory agencies and the courts. The requirements of these programs, including, by way of example, their respective terms and scope, change frequently. Responding to current and future changes may increase our costs, and the complexity of compliance will be time consuming. Invoicing for rebates is provided in arrears, and there is frequently a time lag of up to several months between the sales to which rebate notices relate and our receipt of those notices, which further complicates our ability to accurately estimate and accrue for rebates related to the Medicaid program as implemented by individual states. Thus, there can be no assurance that we will be able to identify all factors that may cause our discount and rebate payment obligations to vary from period to period, and our actual results may differ significantly from our estimated allowances for discounts and rebates. Changes in estimates and assumptions may have an adverse effect on our business, results of operations and financial condition.

In addition, the Office of Inspector General of HHS and other Congressional enforcement and administrative bodies have recently increased their focus on pricing requirements for products, including, but not limited to the methodologies used by manufacturers to calculate average manufacturer price (AMP) and best price (BP) for compliance with reporting requirements under the Medicaid Drug Rebate Program. We are liable for errors associated with our submission of pricing data and for any overcharging of government payers. Failure to make necessary disclosures and/or to identify overpayments could result in allegations against us under the federal False Claims Act and other laws and regulations. Any required refunds to the U.S. government or responding to a government investigation or enforcement action would be expensive and time consuming and could have an adverse effect on our business, results of operations and financial condition. In addition, in the event that CMS were to terminate our rebate agreement, no federal payments would be available under Medicaid for our covered outpatient drugs or under Medicare Part B for any of our products that may be reimbursed under Part B.

Even for those product candidates that have or may receive regulatory approval, they may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success, in which case we may not generate significant revenues or become profitable.

For our product candidates that have or may receive regulatory approval, they may nonetheless fail to gain sufficient market acceptance by physicians, hospital administrators, patients, healthcare payors and others in the medical community. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including the following:

- relative convenience and ease of administration;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the willingness of physicians to change their current treatment practices;
- the willingness of hospitals and hospital systems to include our product candidates as treatment options;
- demonstration of efficacy and safety in clinical trials;
- the prevalence and severity of any side effects;
- the ability to offer product candidates for sale at competitive prices;
- the price we charge for our product candidates;
- the strength of marketing and distribution support; and
- the availability of third-party coverage and adequate reimbursement and the willingness of patients to pay out-of-pocket in the absence of such coverage and adequate reimbursement.

Efforts to educate the physicians, patients, healthcare payors and others in the medical community on the benefits of our product candidates may require significant resources and may not be successful. If any of our product candidates are approved, if at all, but do not achieve an adequate level of acceptance, we may not generate significant product revenue and we may not become profitable on a sustained basis.

We will need additional capital in the future to sufficiently fund our operations and research.*

We have consumed substantial amounts of capital to date as we continue our research and development activities, including preclinical studies and clinical trials and for the commercial launch of TAVALISSE. We may seek another collaborator or licensee in the future for further clinical development and commercialization of fostamatinib, as well as our other clinical programs, which we may not be able to obtain on commercially reasonable terms or at all. We believe that our existing capital resources will be sufficient to support our current and projected funding requirements, including the continued commercial launch of TAVALISSE in the U.S., through at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with commercial launch,

the development of our product candidates and other research and development activities, we are unable to estimate with certainty our future product revenues, our revenues from our current and future collaborative partners, the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials and other research and development activities.

We will continue to need additional capital and the amount of future capital needed will depend largely on the success of our commercial launch of TAVALISSE and the success of our internally developed programs as they proceed in later and more expensive clinical trials, including any additional clinical trials that we may decide to conduct with respect to fostamatinib. While we intend to opportunistically seek access to additional funds through public or private equity offerings or debt financings, we do not know whether additional financing will be available when needed, or that, if available, we will obtain financing on reasonable terms. Our ability to raise additional capital, including our ability to secure new collaborations and continue to support existing collaboration efforts with our partners, may also be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the U.S. and worldwide resulting from the ongoing COVID-19 pandemic. Unless and until we are able to generate a sufficient amount of product, royalty or milestone revenue, which may never occur, we expect to finance future cash needs through public and/or private offerings of equity securities, debt financings or collaboration and licensing arrangements, as well as through proceeds from exercise of stock options and interest income earned on the investment of our cash balances and short-term investments. To the extent we raise additional capital by issuing equity securities in the future, our stockholders could at that time experience substantial dilution. In addition, we have a significant number of stock options outstanding. To the extent that outstanding stock options have been or may be exercised or other shares issued, our stockholders may experience further dilution. Further, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Our credit facility with MidCap involves certain covenants and any other debt financing that we are able to obtain in the future may involve operating covenants that restrict our business. To the extent that we raise additional funds through any new collaboration and licensing arrangements, we may be required to refund certain payments made to us, relinquish some rights to our technologies or product candidates or grant licenses on terms that are not favorable to us.

We have indebtedness in the form of a term loan pursuant to the Credit Agreement with MidCap, which could adversely affect our financial condition and our ability to respond to changes in our business. Further, if we are unable to satisfy certain conditions of the Credit Agreement, we will be unable to draw down the remainder of the facility.

In September 2019, we entered into the Credit Agreement with MidCap. Under the Credit Agreement, we are required to repay amounts due when there is an event of default for the term loans that results in the principal, premium, if any, and interest, if any, becoming due prior to the maturity date for the term loans. The Credit Agreement also contains a number of other affirmative and restrictive covenants. Please see Note 13 to our "Notes to Condensed Financial Statements" contained in Part I, Item 1 of this Quarterly Report on Form 10-Q for additional details of the Credit Agreement. These and other terms in the Credit Agreement have to be monitored closely for compliance and could restrict our ability to grow our business or enter into transactions that we believe would be beneficial to our business. Our business may not generate cash flow from operations in the future sufficient to service our debt and support our growth strategies. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as restructuring our debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our current debt obligations. In addition, we cannot be sure that additional financing will be available when required or, if available, will be on terms satisfactory to us. Further, even if we are able to obtain additional financing, we may be required to use such proceeds to repay a portion of our debt.

Our indebtedness may have other adverse effects, such as:

- our vulnerability to adverse general economic conditions and heightened competitive pressures;
- dedication of a portion of our cash flow from operations to interest payments, limiting the availability of cash for other operational purposes;
- limited flexibility in planning for, or reacting to, changes in our business and industry; and

- our inability to obtain additional financing in the future.

Our Credit Agreement with MidCap contains a mandatory prepayment provision that gives MidCap and/or its Agent the right to demand payment of the outstanding principal and additional interest and fees in the event of default. We may not have enough available cash or be able to obtain financing at the time we are required to repay the term loan with additional interest and fees prior to maturity.

At closing, $10.0 million was funded to us in an initial tranche. The Credit Agreement also gave us the ability to access an additional $50.0 million at our option, of which $40.0 million may be drawn in two tranches subject to the achievement of certain customary conditions. In May 2020, our second tranche of $10.0 million was funded by MidCap. If we are unable to satisfy these or other required conditions, we would not be able to draw down the remaining tranches of financing and may not be able to obtain alternative financing on commercially reasonable terms or at all, which could adversely impact our business.

We rely and may continue to rely on two distribution facilities for the sale of TAVALISSE and potential sale of any of our product candidates.

Our distribution operations for the sale of TAVALISSE is currently concentrated in two distribution centers owned by a third-party logistics provider. Additionally, our distribution operations, if and when we launch any of our product candidates in the future, may also be concentrated in such distribution centers owned by a third-party logistics provider. Any errors in inventory level management and unforeseen inventory shortage could adversely affect our business. In addition, any significant disruption in the operation of the facility due to natural disaster or severe weather, or events such as fire, accidents, power outages, system failures, or other unforeseen causes, could devalue or damage a significant portion of our inventories and could adversely affect our product distribution and sales until such time as we could secure an alternative facility. If we encounter difficulties with any of our distribution facilities, whether due to the impacts of the ongoing COVID-19 pandemic (including as a result of disruptions of global shipping and the transport of products) or otherwise, or other problems or disasters arise, we cannot ensure that critical systems and operations will be restored in a timely manner or at all, and this would have an adverse effect on our business. In addition, growth could require us to further expand our current facility, which could affect us adversely in ways that we cannot predict.

Forecasting potential sales for any of our product candidates will be difficult, and if our projections are inaccurate, our business may be harmed, and our stock price may be adversely affected.

Our business planning requires us to forecast or make assumptions regarding product demand and revenues for any of our product candidates if they are approved despite numerous uncertainties. These uncertainties may be increased if we rely on our collaborators or other third parties to conduct commercial activities in certain geographies and provide us with accurate and timely information. Actual results may differ materially from projected results for various reasons, including the following, as well as risks identified in other risk factors:

- the efficacy and safety of any of our product candidates, including as relative to marketed products and product candidates in development by third parties;
- pricing (including discounting or other promotions), reimbursement, product returns or recalls, competition, labeling, adverse events and other items that impact commercialization;
- the rate of adoption in the particular market, including fluctuations in demand for various reasons;
- impacts due to the ongoing COVID-19 pandemic;
- lack of patient and physician familiarity with the drug;
- lack of patient use and physician prescribing history;
- lack of commercialization experience with the drug;
- actual sales to patients may significantly differ from expectations based on sales to wholesalers; and
- uncertainty relating to when the drug may become commercially available to patients and rate of adoption

in other territories.

We expect that our revenues from sales of any of our product candidates will continue to be based in part on estimates, judgment and accounting policies. Any incorrect estimates or disagreements with regulators or others regarding such estimates or accounting policies may result in changes to our guidance, projections or previously reported results. Expected and actual product sales and quarterly and other results may greatly fluctuate, including in the near-term, and such fluctuations can adversely affect the price of our common stock, perceptions of our ability to forecast demand and revenues, and our ability to maintain and fund our operations.

We do not and will not have access to all information regarding fostamatinib and product candidates we licensed to Lilly, Kissei, Grifols and Medison.*

We do not and will not have access to all information regarding fostamatinib and other product candidates, including potentially material information about commercialization plans, medical information strategies, clinical trial design and execution, safety reports from clinical trials, safety reports, regulatory affairs, process development, manufacturing and other areas known by Lilly, Kissei, Grifols and Medison. In addition, we have confidentiality obligations under our respective agreements with Lilly, Kissei, Grifols and Medison. Thus, our ability to keep our shareholders informed about the status of fostamatinib and other product candidates will be limited by the degree to which Lilly, Kissei, Grifols and/or Medison keep us informed and allows us to disclose such information to the public. If Lilly, Kissei, Grifols and/or Medison fail to keep us informed about commercialization efforts related to fostamatinib, or the status of the clinical development or regulatory approval pathway of other product candidates licensed to them, we may make operational and/or investment decisions that we would not have made had we been fully informed, which may adversely affect our business and operations.

Our future funding requirements will depend on many uncertain factors.

Our future funding requirements will depend upon many factors, many of which are beyond our control, including, but not limited to:

- the costs to commercialize fostamatinib for the treatment of ITP in the United States, or any other future product candidates, if any such candidate receives regulatory approval for commercial sale;
- the progress and success of our clinical trials and preclinical activities (including studies and manufacture of materials) of our product candidates conducted by us;
- any current and future impacts of the ongoing and evolving COVID-19 pandemic;
- the costs and timing of regulatory filings and approvals by us and our collaborators;
- the progress of research and development programs carried out by us and our collaborative partners;
- any changes in the breadth of our research and development programs;
- the ability to achieve the events identified in our collaborative agreements that may trigger payments to us from our collaboration partners;
- our ability to acquire or license other technologies or compounds that we may seek to pursue;
- our ability to manage our growth;
- competing technological and market developments;
- the costs and timing of obtaining, enforcing and defending our patent and other intellectual property rights; and
- expenses associated with any unforeseen litigation, including any arbitration and securities class action lawsuits.

Insufficient funds may require us to delay, scale back or eliminate some or all of our commercial efforts and/or research and development programs, to reduce personnel and operating expenses, to lose rights under existing licenses or to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose or may adversely affect our ability to operate as a going concern.

Our success as a company is uncertain due to our history of operating losses and the uncertainty of any future profitability. *

We recognized an income from operations of approximately $8.9 million during the nine months ended September 30, 2021 primarily due to the timing of recognition of revenue from the Lilly Agreement and grant from the U.S. Department of Defense, partly offset by cost and expenses incurred. We historically incurred losses from operations each year since we were incorporated in June 1996 other than in fiscal year 2010, due in large part to the significant research and development expenditures required to identify and validate new product candidates and pursue our development efforts, and the costs of our ongoing commercial efforts for TAVALISSE. We expect to continue to incur losses from operations, at least in the next 12 months, and there can be no assurance that we will generate annual operating income in the foreseeable future. Currently, our potential sources of revenues are our sales of TAVALISSE, upfront payments, research and development contingent payments and royalty payments pursuant to our collaboration arrangements, which may never materialize if our collaborators do not achieve certain events or generate net sales to which these contingent payments are dependent on. If our future drug candidates fail or do not gain regulatory approval, or if our drugs do not achieve sustainable market acceptance, we may not be profitable. As of September 30, 2021, we had an accumulated deficit of approximately $1.3 billion. The extent of our future losses or profitability, if any, especially due to the ongoing COVID-19 pandemic, is highly uncertain.

If our corporate collaborations or license agreements are unsuccessful, or if we fail to form new corporate collaborations or license agreements, our research and development efforts could be delayed.

Our strategy depends upon the formation and sustainability of multiple collaborative arrangements and license agreements with third parties now and in the future. We rely on these arrangements for not only financial resources, but also for expertise we need now and in the future relating to clinical trials, manufacturing, sales and marketing, and for licenses to technology rights. To date, we have entered into several such arrangements with corporate collaborators; however, we do not know if these collaborations or additional collaborations with third parties, if any, will dedicate sufficient resources or if any development or commercialization efforts by third parties will be successful. In addition, our corporate collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a drug candidate or development program. Should a collaborative partner fail to develop or commercialize a compound or product to which it has rights from us for any reason, including corporate restructuring, such failure might delay our ongoing research and development efforts, because we might not receive any future payments, and we would not receive any royalties associated with such compound or product. We are conducting a Phase 3 clinical program to study fostamatinib in wAIHA on our own. We may seek another collaborator or licensee in the future for clinical development and commercialization of fostamatinib, as well as our other clinical programs, which we may not be able to obtain on commercially reasonable terms or at all. If we are unable to form new collaborations or enter into new license agreements, our research and development efforts could be delayed. In addition, the continuation of some of our partnered drug discovery and development programs may be dependent on the periodic renewal of our corporate collaborations.

Each of our collaborations could be terminated by the other party at any time, and we may not be able to renew these collaborations on acceptable terms, if at all, or negotiate additional corporate collaborations on acceptable terms, if at all. If these collaborations terminate or are not renewed, any resultant loss of revenues from these collaborations or loss of the resources and expertise of our collaborative partners could adversely affect our business.

Conflicts also might arise with collaborative partners concerning proprietary rights to particular compounds. While our existing collaborative agreements typically provide that we retain milestone payments, royalty rights and/or revenue sharing with respect to drugs developed from certain compounds or derivative compounds, any such payments or royalty rights may be at reduced rates, and disputes may arise over the application of payment provisions or derivative payment provisions to such drugs, and we may not be successful in such disputes. For example, in September 2018, BerGenBio served us with a notice of arbitration seeking declaratory relief related to the interpretation of provisions under our June 2011 license agreement, particularly as they relate to the rights and obligations of the parties in the event of the license or sale of a product in the program by BerGenBio and/or the sale of BerGenBio to a third party. The

arbitration panel dismissed four of the six declarations sought by BerGenBio, and we thereafter consented to one of the remaining declarations requested by BerGenBio. On February 27, 2019, the arbitration panel issued a determination granting the declaration sought by BerGenBio on the remaining issue, and held that in the event of a sale of shares by BerGenBio's shareholders where there is no monetary benefit to BerGenBio, we would not be entitled to a portion of the proceeds from such a sale. In this circumstance where the revenue share provision is not triggered, the milestone and royalty payment provisions remain in effect. While we do not believe that the determination will have an adverse effect on our operations, cash flows or financial condition, we can make no assurance regarding any such impact. Additionally, the management teams of our collaborators may change for various reasons including due to being acquired. Different management teams or an acquiring company of our collaborators may have different priorities which may have adverse results on the collaboration with us.

We are also a party to various license agreements that give us rights to use specified technologies in our research and development processes. The agreements pursuant to which we have in-licensed technology permit our licensors to terminate the agreements under certain circumstances. If we are not able to continue to license these and future technologies on commercially reasonable terms, our product development and research may be delayed or otherwise adversely affected.

If conflicts arise between our collaborators or advisors and us, any of them may act in their self-interest, which may be adverse to our stockholders' interests.

If conflicts arise between us and our corporate collaborators or scientific advisors, the other party may act in its self-interest and not in the interest of our stockholders. Some of our corporate collaborators are conducting multiple product development efforts within each disease area that is the subject of the collaboration with us or may be acquired or merged with a company having a competing program. In some of our collaborations, we have agreed not to conduct, independently or with any third party, any research that is competitive with the research conducted under our collaborations. Our collaborators, however, may develop, either alone or with others, products in related fields that are competitive with the products or potential products that are the subject of these collaborations. Competing products, either developed by our collaborators or to which our collaborators have rights, may result in their withdrawal of support for our product candidates.

If any of our corporate collaborators were to breach or terminate its agreement with us or otherwise fail to conduct the collaborative activities successfully and in a timely manner, the preclinical or clinical development or commercialization of the affected product candidates or research programs could be delayed or terminated. We generally do not control the amount and timing of resources that our corporate collaborators devote to our programs or potential products. We do not know whether current or future collaborative partners, if any, might pursue alternative technologies or develop alternative products either on their own or in collaboration with others, including our competitors, as a means for developing treatments for the diseases targeted by collaborative arrangements with us.

Our success is dependent on intellectual property rights held by us and third parties, and our interest in such rights is complex and uncertain.

Our success will depend to a large part on our own, our licensees' and our licensors' ability to obtain and defend patents for each party's respective technologies and the compounds and other products, if any, resulting from the application of such technologies. For example, fostamatinib is covered as a composition of matter in a U.S. issued patent that has an expected expiration date of September 2031, after taking into account patent term adjustment and extension rules.

In the future, our patent position might be highly uncertain and involve complex legal and factual questions. For example, we may be involved in post-grant proceedings before the United States Patent and Trademark Office. Post-grant proceedings are complex and expensive legal proceedings and there is no assurance we will be successful in any such proceedings. A post-grant proceeding could result in our losing our patent rights and/or our freedom to operate and/or require us to pay significant royalties. Additionally, third parties may challenge the validity, enforceability or scope of our issued patents, which may result in such patents being narrowed, invalidated or held unenforceable through interference, opposition or invalidity proceedings before the United States Patent and Trademark Office or non-U.S. patent offices. Any successful opposition to our patents could deprive us of exclusive rights necessary for the successful commercialization of fostamatinib or our other product candidates. Oppositions could also be filed to complementary patents, such as formulations, methods of manufacture and methods of use, that are intended to extend the patent life of

the overall portfolio beyond the patent life covering the composition of matter. A successful opposition to any such complementary patent could impact our ability to extend the life of the overall portfolio beyond that of the related composition of matter patent.

Additional uncertainty may result because no consistent policy regarding the breadth of legal claims allowed in biotechnology patents has emerged to date. Accordingly, we cannot predict the breadth of claims allowed in our or other companies' patents.

Because the degree of future protection for our proprietary rights is uncertain, we cannot assure you that:

- we were the first to make the inventions covered by each of our pending;
- we were the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies;
- any of our pending patent applications will result in issued patents;
- any patents issued to us or our collaborators will provide a basis for commercially viable products or will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies that are patentable; or
- the patents of others will not have a negative effect on our ability to do business.

We rely on trade secrets to protect technology where we believe patent protection is not appropriate or obtainable; however, trade secrets are difficult to protect. While we require employees, collaborators and consultants to enter into confidentiality agreements, we may not be able to adequately protect our trade secrets or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of such information.

We are a party to certain in-license agreements that are important to our business, and we generally do not control the prosecution of in-licensed technology. Accordingly, we are unable to exercise the same degree of control over this intellectual property as we exercise over our internally developed technology. Moreover, some of our academic institution licensors, research collaborators and scientific advisors have rights to publish data and information in which we have rights. If we cannot maintain the confidentiality of our technology and other confidential information in connection with our collaborations, our ability to receive patent protection or protect our proprietary information may otherwise be impaired. In addition, some of the technology we have licensed relies on patented inventions developed using U.S. government resources.

The U.S. government retains certain rights, as defined by law, in such patents, and may choose to exercise such rights. Certain of our in-licenses may be terminated if we fail to meet specified obligations. If we fail to meet such obligations and any of our licensors exercise their termination rights, we could lose our rights under those agreements. If we lose any of our rights, it may adversely affect the way we conduct our business. In addition, because certain of our licenses are sublicenses, the actions of our licensors may affect our rights under those licenses.

If a dispute arises regarding the infringement or misappropriation of the proprietary rights of others, such dispute could be costly and result in delays in our research and development activities and partnering.

Our success will depend, in part, on our ability to operate without infringing or misappropriating the proprietary rights of others. There are many issued patents and patent applications filed by third parties relating to products or processes that are similar or identical to our licensors or ours, and others may be filed in the future. There may also be copyrights or trademarks that third parties hold. There can be no assurance that our activities, or those of our licensors, will not violate intellectual property rights of others. We believe that there may be significant litigation in the industry regarding patent and other intellectual property rights, and we do not know if our collaborators or we would be successful in any such litigation. Any legal action against our collaborators or us claiming damages or seeking to enjoin commercial activities relating to the affected products, our methods or processes could:

- require our collaborators or us to obtain a license to continue to use, manufacture or market the affected products, methods or processes, which may not be available on commercially reasonable terms, if at all;
- prevent us from using the subject matter claimed in the patents held by others;
- subject us to potential liability for damages;
- consume a substantial portion of our managerial and financial resources; and
- result in litigation or administrative proceedings that may be costly, whether we win or lose.

Our effective tax rate may fluctuate, and we may incur obligations in tax jurisdictions in excess of accrued amounts.

We are subject to taxation in numerous U.S. states and territories. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various places that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of such places. Nevertheless, our effective tax rate may be different than experienced in the past due to numerous factors, including passage of the newly enacted federal income tax law, changes in the mix of our profitability from state to state, the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities, changes in accounting for income taxes and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations and may result in tax obligations in excess of amounts accrued in our financial statements.

Our ability to use net operating losses and certain other tax attributes is uncertain and may be limited.

Our ability to use our federal and state NOLs to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income before the expiration dates of the NOLs, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our NOLs. Federal NOLs generated prior to 2018 will continue to be governed by the NOL carryforward rules as they existed prior to the adoption of the Tax Act, which means that generally they will expire 20 years after they were generated if not used prior thereto. Many states have similar laws. Accordingly, our federal and state NOLs could expire unused and be unavailable to offset future income tax liabilities. Under the Tax Act as modified by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), federal NOLs incurred in tax years beginning after December 31, 2017 and before January 1, 2021 may be carried back to each of the five tax years preceding such loss, and NOLs arising in tax years beginning after December 31, 2020 may not be carried back. Moreover, federal net operating losses generated in tax years ending after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs may be limited to 80% of current year taxable income for tax years beginning after January 1, 2021. Under A.B. 85, the Company's California net operating loss carryforwards are suspended for tax years 2020, 2021, and 2022, but the period to use these carryovers was extended.

In addition, utilization of net operating losses to offset potential future taxable income and related income taxes that would otherwise be due is subject to annual limitations under the "ownership change" provisions of Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (Code) and similar state provisions, which may result in the expiration of net operating losses before future utilization. In general, under the Code, if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating losses and other pre-change tax attributes (such as research and development credit carryforwards) to offset its post-change taxable income or taxes may be limited. Our equity offerings and other changes in our stock ownership, some of which are outside of our control, may have resulted or could in the future result in an ownership change. Although we have completed studies to provide reasonable assurance that an ownership change limitation would not apply, we cannot be certain that a taxing authority would reach the same conclusion. If, after a review or audit, an ownership change limitation were to apply, utilization of our domestic net operating losses and tax credit carryforwards could be limited in future periods and a portion of the carryforwards could expire before being available to reduce future income tax liabilities. Moreover, our ability to utilize our net operating losses is conditioned upon us achieving profitability and generating U.S. federal taxable income.

Because we expect to be dependent upon collaborative and license agreements, we might not meet our strategic objectives.

Our ability to generate revenue in the near term depends on the timing of recognition of certain upfront payments, achievement of certain payment triggering events with our existing collaboration agreements and our ability to enter into additional collaborative agreements with third parties. Our ability to enter into new collaborations and the revenue, if any, that may be recognized under these collaborations is highly uncertain. If we are unable to enter into one or more new collaborations, our business prospects could be harmed, which could have an immediate adverse effect on our ability to continue to develop our compounds and on the trading price of our stock. Our ability to enter into a collaboration may be dependent on many factors, such as the results of our clinical trials, competitive factors and the fit of one of our programs with another company's risk tolerance, including toward regulatory issues, patent portfolio, clinical pipeline, the stage of the available data, particularly if it is early, overall corporate goals and financial position.

To date, a portion of our revenues have been related to the research or transition phase of each of our collaborative agreements. Such revenues are for specified periods, and the impact of such revenues on our results of operations is at least partially offset by corresponding research costs. Following the completion of the research or transition phase of each collaborative agreement, additional revenues may come only from payments triggered by milestones and/or the achievement of other contingent events, and royalties, which may not be paid, if at all, until certain conditions are met. This risk is heightened due to the fact that unsuccessful research efforts may preclude us from receiving any contingent payments under these agreements. Our receipt of revenues from collaborative arrangements is also significantly affected by the timing of efforts expended by us and our collaborators and the timing of lead compound identification. We have received payments from our collaborations with Lilly, Grifols, Kissei, Medison, Aclaris, Celgene, BMS, AZ, BerGenBio, Janssen Pharmaceutica N.V., a division of Johnson & Johnson, Novartis Pharma A.G., Daiichi, Merck & Co., Inc., Merck Serono and Pfizer. Under many agreements, future payments may not be earned until the collaborator has advanced product candidates into clinical testing, which may never occur or may not occur until sometime well into the future. If we are not able to generate revenue under our collaborations when and in accordance with our expectations or the expectations of industry analysts, this failure could harm our business and have an immediate adverse effect on the trading price of our common stock.

Our business requires us to generate meaningful revenue from royalties and licensing agreements. To date, we have not received any revenue from royalties for the commercial sale of drugs, and we do not know when we will receive any such revenue, if at all.

Securities class action lawsuits or other litigation could result in substantial damages and may divert management's time and attention from our business.

We have been subject to class action lawsuits in the past and we may be subject to lawsuits in the future, such as those that might occur if there was to be a change in our corporate strategy. These and other lawsuits are subject to inherent uncertainties, and the actual costs to be incurred relating to the lawsuit will depend upon many unknown factors. The outcome of litigation is necessarily uncertain, and we could be forced to expend significant resources in the defense of such suits, and we may not prevail. Monitoring and defending against legal actions is time-consuming for our management and detracts from our ability to fully focus our internal resources on our business activities. In addition, we may incur substantial legal fees and costs in connection with any such litigation. We have not established any reserves for any potential liability relating to any such potential lawsuits. It is possible that we could, in the future, incur judgments or enter into settlements of claims for monetary damages. A decision adverse to our interests on any such actions could result in the payment of substantial damages, or possibly fines, and could have an adverse effect on our cash flow, results of operations and financial position.

If our competitors develop technologies that are more effective than ours, our commercial opportunity will be reduced or eliminated.*

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Many of the drugs that we are attempting to discover will be competing with existing therapies. In addition, a number of companies are pursuing the development of pharmaceuticals that target the same diseases and conditions that we are targeting. For example, the commercialization of new pharmaceutical products is highly competitive, and we face substantial competition with respect to TAVALISSE in which there are existing therapies and

drug candidates in development for the treatment of ITP that may be alternative therapies to TAVALISSE. Many of our competitors, including a number of large pharmaceutical companies that compete directly with us, have significantly greater financial resources and expertise commercializing approved products than we do. Also, many of our competitors are large pharmaceutical companies that will have a greater ability to reduce prices for their competing drugs in an effort to gain market share and undermine the value proposition that we might otherwise be able to offer to payers. We face, and will continue to face, intense competition from pharmaceutical and biotechnology companies, as well as from academic and research institutions and government agencies, both in the United States and abroad. Some of these competitors are pursuing the development of pharmaceuticals that target the same diseases and conditions as our research programs. Our competitors including fully integrated pharmaceutical companies have extensive drug discovery efforts and are developing novel small-molecule pharmaceuticals. We also face significant competition from organizations that are pursuing the same or similar technologies, including the discovery of targets that are useful in compound screening, as the technologies used by us in our drug discovery efforts.

Competition may also arise from:

- new or better methods of target identification or validation;
- generic version of TAVALISSE or of products with which we compete;
- other drug development technologies and methods of preventing or reducing the incidence of disease;
- new small molecules; or
- other classes of therapeutic agents.

Our competitors or their collaborative partners may utilize discovery technologies and techniques or partner with collaborators in order to develop products more rapidly or successfully than we or our collaborators are able to do. Many of our competitors, particularly large pharmaceutical companies, have substantially greater financial, technical and human resources and larger research and development staffs than we do. In addition, academic institutions, government agencies and other public and private organizations conducting research may seek patent protection with respect to potentially competitive products or technologies and may establish exclusive collaborative or licensing relationships with our competitors.

We believe that our ability to compete is dependent, in part, upon our ability to create, maintain and license scientifically-advanced technology and upon our and our collaborators' ability to develop and commercialize pharmaceutical products based on this technology, as well as our ability to attract and retain qualified personnel, obtain patent protection or otherwise develop proprietary technology or processes, secure effective market access by ensuring competitive pricing and reimbursement in territories of interest, and secure sufficient capital resources for the expected substantial time period between technological conception and commercial sales of products based upon our technology. The failure by any of our collaborators or us in any of those areas may prevent the successful commercialization of our potential drug targets.

Many of our competitors, either alone or together with their collaborative partners, have significantly greater experience than we do in:

- identifying and validating targets;
- screening compounds against targets; and
- undertaking preclinical testing and clinical trials.

Accordingly, our competitors may succeed in obtaining patent protection, identifying or validating new targets or discovering new drug compounds before we do.

Our competitors might develop technologies and drugs that are more effective or less costly than any that are being developed by us or that would render our technology and product candidates obsolete and noncompetitive. In addition, our competitors may succeed in obtaining the approval of the FDA or other regulatory agencies for product candidates more rapidly. Companies that complete clinical trials, obtain required regulatory agency approvals and

commence commercial sale of their drugs before us may achieve a significant competitive advantage, including certain patent and FDA marketing exclusivity rights that would delay or prevent our ability to market certain products. Any drugs resulting from our research and development efforts, or from our joint efforts with our existing or future collaborative partners, might not be able to compete successfully with competitors' existing or future products or obtain regulatory approval in the United States or elsewhere.

We face and will continue to face intense competition from other companies for collaborative arrangements with pharmaceutical and biotechnology companies, for establishing relationships with academic and research institutions and for licenses to additional technologies. These competitors, either alone or with their collaborative partners, may succeed in developing technologies or products that are more effective than ours.

Our ability to compete successfully will depend, in part, on our ability to:

- identify and validate targets;
- discover candidate drug compounds that interact with the targets we identify in a safe and efficacious way;
- attract and retain scientific and product development personnel;
- recruit subjects into our clinical trials;
- obtain and maintain required regulatory approvals;
- obtain patent or other proprietary protection for our new drug compounds and technologies; and
- enter commercialization agreements for our new drug compounds.

Our stock price may be volatile, and our stockholders' investment in our common stock could decline in value.

The market prices for our common stock and the securities of other biotechnology companies have been highly volatile and may continue to be highly volatile in the future. 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:

- the progress and success of our clinical trials and preclinical activities (including studies and manufacture of materials) of our product candidates conducted by us;
- our ability to continue to sell TAVALISSE in the United States;
- our ability to enter into partnering opportunities across our pipeline;
- the receipt or failure to receive the additional funding necessary to conduct our business;
- selling of our common stock by large stockholders;
- presentations of detailed clinical trial data at medical and scientific conferences and investor perception thereof;
- announcements of technological innovations or new commercial products by our competitors or us;
- developments concerning proprietary rights, including patents;
- developments concerning our collaborations;
- publicity regarding actual or potential medical results relating to products under development by our competitors or us;
- regulatory developments in the United States and foreign countries;
- changes in the structure of healthcare payment systems;

- litigation or arbitration;
- economic and other external factors or other disaster or crisis; and
- period-to-period fluctuations in financial results.

The withdrawal of the UK from the EU may adversely impact our ability to obtain regulatory approvals of our product candidates in the UK and the EU, result in restrictions or imposition of taxes and duties for importing our product candidates into the UK and the EU, and may require us to incur additional expenses in order to develop, manufacture and commercialize our product candidates in the UK and the EU

Following the result of a referendum in 2016, the UK left theEU on January 31, 2020, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed between the UK and the EU, the UK was subject to a transition period until December 31, 2020, or the Transition Period, during which EU rules continued to apply. A trade and cooperation agreement, (Trade Agreement), that outlines the future trading relationship between the UK and the EU was agreed in December 2020 and has been approved by each EU member state and the UK.

Since a significant proportion of the regulatory framework in the UK applicable to our business and our product candidates is derived from EU directives and regulations, Brexit has had, and will continue to have, a material impact upon the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the UK or the EU Great Britain (made up of England, Scotland, and Wales) is no longer covered by the EEA's procedures for the grant of marketing authorizations (Northern Ireland will be covered by such procedures). A separate marketing authorization will be required to market drugs in Great Britain. It is currently unclear whether the Medicines and Healthcare Products Regulatory Agency, or MHRA, in the UK is sufficiently prepared to handle the increased volume of marketing authorization applications that it is likely to receive. Any delay in obtaining, or an inability to obtain, any marketing approvals, would delay or prevent us from commercializing our product candidates in the UK or the EU and restrict our ability to generate revenue and achieve and sustain profitability.

While the Trade Agreement provides for the tariff-free trade of medicinal products between the UK and the EU there may be additional non-tariff costs to such trade which did not exist prior to the end of the Transition Period. Further, should the UK diverge from the EU from a regulatory perspective in relation to medicinal products, tariffs could be put into place in the future. We could therefore, both now and in the future, face significant additional expenses (when compared to the position prior to the end of the Transition Period) to operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the UK It is also possible that Brexit may negatively affect our ability to attract and retain employees, particularly those from the EU.

Orphan designation in Great Britain following Brexit is granted on an essentially identical basis to in the EU but is based on the prevalence of the condition in Great Britain. It is therefore possible that conditions that are currently designated as orphan conditions in Great Britain will no longer be and that conditions that are not currently designated as orphan conditions in the EU will be designated as such in Great Britain.

If product liability lawsuits are successfully brought against us, we may incur substantial liabilities and may be required to limit commercialization of our products.

The testing and marketing of medical products and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products. We carry product liability insurance that is limited in scope and amount and may not be adequate to fully protect us against product liability claims. If and when we obtain marketing approval for our product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we

develop, alone or with corporate collaborators. We, or our corporate collaborators, might not be able to obtain insurance at a reasonable cost, if at all. While under various circumstances we are entitled to be indemnified against losses by our corporate collaborators, indemnification may not be available or adequate should any claim arise.

We depend on various scientific consultants and advisors for the success and continuation of our research and development efforts.

We work extensively with various scientific consultants and advisors. The potential success of our drug discovery and development programs depends, in part, on continued collaborations with certain of these consultants and advisors. We, and various members of our management and research staff, rely on certain of these consultants and advisors for expertise in our research, regulatory and clinical efforts. Our scientific advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. We do not know if we will be able to maintain such consulting agreements or that such scientific advisors will not enter into consulting arrangements, exclusive or otherwise, with competing pharmaceutical or biotechnology companies, any of which would have a detrimental impact on our research objectives and could have an adverse effect on our business, financial condition and results of operations.

If we use biological and hazardous materials in a manner that causes injury or violates laws, we may be liable for damages, penalties or fines.

Our research and development activities involve the controlled use of potentially harmful biological materials as well as hazardous materials, chemicals, animals, and various radioactive compounds. We cannot completely eliminate the risk of accidental contamination or injury from the use, storage, handling or disposal of these animals and materials. In the event of contamination or injury, we could be held liable for damages that result or for penalties or fines that may be imposed, and such liability could exceed our resources. We are also subject to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The cost of compliance with, or any potential violation of, these laws and regulations could be significant.

Our information technology systems, or those used by our CROs or other contractors or consultants, may fail or suffer other breakdowns, cyber-attacks, or information security breaches.*

We are increasingly dependent upon information technology systems, infrastructure, and data to operate our business, particularly during the COVID-19 pandemic. We also rely on third party vendors and their information technology systems. Despite the implementation of security measures, our recovery systems, security protocols, network protection mechanisms and other security measures and those of our CROs and other contractors and consultants are vulnerable to compromise from natural disasters; terrorism; war; telecommunication and electric failures; traditional computer hackers; malicious code (such as computer viruses or worms); employee error, theft or misuse; denial-of-service attacks; cyber-attacks by sophisticated nation-state and nation-state supported actors including ransomware; or other system disruptions. We receive, generate and store significant and increasing volumes of personal (including health), confidential and proprietary information. There can be no assurance that we, or our collaborators, CROs, third-party vendors, contractors and consultants, will be successful in efforts to detect, prevent, protect against or fully recover systems or data from all break-downs, service interruptions, attacks or breaches. Any breakdown, cyber-attack or information security breach could result in a disruption of our drug development programs or other aspects of our business. For example, the loss of clinical trial data from completed or ongoing clinical trials for a product candidate could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability, incur significant remediation or litigation costs, result in product development delays, disrupt key business operations, cause loss of revenue and divert attention of management and key information technology resources.

Hackers and data thieves are increasingly sophisticated and operating large-scale and complex automated attacks, including on companies within the healthcare industry. As the cyber-threat landscape evolves, these threats will likely grow in frequency, sophistication and intensity and may become increasingly difficult to detect. The costs of maintaining or upgrading our cyber-security systems at the level necessary to keep up with our expanding operations and prevent against potential attacks are increasing. Cyber threats may be generic, or they may be targeted against our information systems. Our network and storage applications and those of our contract manufacturing organizations,

collaborators, contractors, CROs or vendors may be subject to unauthorized access or processing by hackers or breached due to operator or other human error, theft, malfeasance or other system disruptions. We may be unable to anticipate or immediately detect information security incidents and the damage caused by such incidents. These data breaches and any unauthorized access, processing or disclosure of our information or intellectual property could compromise our intellectual property and expose our sensitive business information. Because our services involve the processing of personal information and other sensitive information about individuals we are subject to various laws, regulations, industry standards, and contractual requirements related to such processing. Any event that leads to unauthorized access, processing or disclosure of personal information, including personal information regarding our clinical study participants or employees, could harm our reputation and business, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to investigations and mandatory corrective action, and otherwise subject us to liability under laws, regulations or contracts that protect the privacy and security of personal information, which could disrupt our business, damage our reputation with our stakeholders, result in increased costs or loss of revenue, lead to negative publicity or result in significant financial exposure. The CCPA, in particular, includes a private right of action for California consumers whose personal information is impacted by a data security incident resulting from a company's failure to maintain reasonable security procedures, and hence may result in civil litigation in the event of a security breach impacting such information. In addition, legislators and regulators in the U.S. have enacted and are proposing new and more robust privacy and cybersecurity laws and regulations in response to increasing broad-based cyberattacks, including the CCPA and New York SHIELD Act. New data security laws add additional complexity, requirements, restrictions and potential legal risk and compliance programs may require additional investment in resources, and could impact strategies and availability of previously useful data.

The costs to respond to a security breach and/or to mitigate any identified security vulnerabilities could be significant, our efforts to address these issues may not be successful, and these issues could result in interruptions, delays, negative publicity, loss of customer trust, and other harms to our business and competitive position. Remediation of any potential security breach may involve significant time, resources, and expenses. We could be required to fundamentally change our business activities and practices in response to a security breach and our systems or networks may be perceived as less desirable, which could negatively affect our business and damage our reputation.

A security breach may cause us to breach our contracts with third parties. Our agreements with relevant stakeholders such as collaborators may require us to use legally required, industry-standard or reasonable measures to safeguard personal information. A security breach could lead to claims by relevant stakeholders that we have failed to comply with such contractual obligations, or require us to cooperate with these stakeholders in their own compliance efforts related to the security breach. In addition, any non-compliance with our data privacy obligations in our contracts or our inability to flow down such obligations from relevant stakeholders to our vendors may cause us to breach our contracts. As a result, we could be subject to legal action or the relevant stakeholders could end their relationships with us. There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages.

We may not have adequate insurance coverage for security incidents or breaches. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that its existing insurance coverage will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim.

Future equity issuances or a sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.*

Because we will continue to need additional capital in the future to continue to expand our business and our research and development activities, among other things, we may conduct additional equity offerings. For example, we filed a universal shelf registration statement in March 2018 that was declared effective by the SEC in April 2018, and expired in April 2021, under which we sold 18,400,000 shares of common stock at a weighted-average price of $3.90 per share for net proceeds of $67.2 million, after deducting sale commissions. On August 3, 2021, we filed a new automatic shelf registration statement to register an additional $100.0 million of shares of our common stock for sale under our Open Market Sale Agreement with Jefferies. We may also in the future enter into underwriting or sales agreements with financial institutions for the offer and sale of any combination of common stock, preferred stock, debt securities and

warrants in one or more offerings. If we or our stockholders sell, or if it is perceived that we or they will sell, substantial amounts of our common stock in the public market, the market price of our common stock could fall. A decline in the market price of our common stock could make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem appropriate. In addition, future sales by us of our common stock may be dilutive to existing stockholders. Furthermore, if we obtain funds through a credit facility or through the issuance of debt or preferred securities, these securities would likely have rights senior to the rights of our common stockholders, which could impair the value of our common stock.

Risks Related to Clinical Development and Regulatory Approval

Enacted or future legislation, and/or potentially unfavorable pricing regulations or other healthcare reform initiatives, may increase the difficulty and cost for us to obtain regulatory approval of our product candidates and/or commercialize fostamatinib or our product candidates, once approved, and affect the prices we may set or obtain.*

The regulations that govern, among other things, regulatory approvals, coverage, pricing and reimbursement for new drug products vary widely from country to country. In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay regulatory approval of our product candidates, restrict or regulate post-approval activities and affect our ability to successfully sell fostamatinib or any product candidates for which we obtain regulatory approval in the future. In particular, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the Affordable Care Act, was enacted, which substantially changed the way health care is financed by both governmental and private insurers, and continues to significantly impact the U.S. pharmaceutical industry. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the Affordable Care Act brought by several states without specifically ruling on the constitutionality of the law. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace, which began on February 15, 2021 and remained open through August 15, 2021. The executive order instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. It is unclear how the Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration will impact the Affordable Care Act and our business.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect, for example:

- the demand for fostamatinib or our product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Additionally, any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

In the United States, the EU and other potentially significant markets for our current and future products, government authorities and third-party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. In the United States, there have been several recent Congressional inquiries and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer-sponsored patient assistance programs, and reform government program reimbursement methodologies for drugs. The Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. The FDA also released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the Department of Health and Human Services (HHS) finalized a regulation removing safe harbor protection under the federal Anti-Kickback Statute for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor manufacturer for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed until January 1, 2023. Most recently, the bipartisan infrastructure legislation passed by the U.S. Senate in August 2021 included a moratorium on implementation of the safe harbor reforms before January 1, 2026; however it is unclear whether or when such legislation will be enacted. On November 20, 2020, the Centers for Medicare & Medicaid Services (CMS) also issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which, among other changes, eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacture price, for single source and innovator multiple source drugs, beginning January 1, 2024. The Biden administration has begun taking executive actions to address drug pricing and other healthcare policy changes, including reversing certain measures by the Trump administration. For example, on July 9, 2021, President Biden signed an executive order to promote competition in the U.S. economy that included several initiatives addressing prescription drugs. Among other provisions, the executive order directed the Secretary of HHS to issue a report to the White House within 45 days that includes a plan to, among other things, reduce prices for prescription drugs, including prices paid by the federal government for such drugs. Additionally, on August 10, 2021, CMS issued a proposed rule proposing to rescind the Most Favored Nation model interim final rule.

Furthermore, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the EU will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our sales and results of operations. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. It is also possible that additional governmental action is taken in response to the COVID-19 pandemic.

We cannot predict the likelihood, nature, or extent of health reform initiatives that may arise from future legislation or administrative action, particularly as a result of the new presidential administration. However, we expect these initiatives to increase pressure on drug pricing. Further, certain broader legislation that is not targeted to the health care industry may nonetheless adversely affect our profitability. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

See section titled "Business – Government Regulation – Healthcare Reform" in Part I, Item 1 of our Annual Report on Form 10-K filed on March 2, 2021 for more information on healthcare reform activities.

Regulatory approval for any approved product is limited by the FDA, the European Commission and other regulators to those specific indications and conditions for which clinical safety and efficacy have been demonstrated, and we may incur significant liability if it is determined that we are promoting the "off-label" use of TAVALISSE or any of our future product candidates if approved.

Any regulatory approval is limited to those specific diseases, indications and patient populations for which a product is deemed to be safe and effective by the FDA, the European Commission and other regulators. For example, the FDA-approved label for TAVALISSE is only approved for use in adults with ITP who have had an insufficient response to other treatments. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. If we are not able to obtain FDA approval for any desired future indications for our products and product candidates, our ability to effectively market and sell our products may be reduced and our business may be adversely affected.

While physicians may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical studies and approved by the regulatory authorities, our ability to promote the products is limited to those indications and patient populations that are specifically approved by the FDA. These "off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. We have implemented compliance and monitoring policies and procedures, including a process for internal review of promotional materials, to deter the promotion of TAVALISSE for off-label uses. We cannot guarantee that these compliance activities will prevent or timely detect off-label promotion by sales representatives or other personnel in their communications with health care professionals, patients and others, particularly if these activities are concealed from the Company. Regulatory authorities in the United States generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off-label use. If our promotional activities fail to comply with the FDA's or other competent national authority's regulations or guidelines, we may be subject to warnings from, or enforcement action by, these regulatory authorities. In addition, our failure to follow FDA rules and guidelines relating to promotion and advertising may cause the FDA to issue warning letters or untitled letters, suspend or withdraw an approved product from the market, require a recall or institute fines, which could result in the disgorgement of money, operating restrictions, injunctions or civil or criminal enforcement, and other consequences, any of which could harm our business.

Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading and non-promotional scientific exchange concerning their products. We engage in medical education activities and communicate with investigators and potential investigators regarding our clinical trials. If the FDA or other regulatory or enforcement authorities determine that our communications regarding our marketed product are not in compliance with the relevant regulatory requirements and that we have improperly promoted off-label uses, or that our communications regarding our investigational products are not in compliance with the relevant regulatory requirements and that we have improperly engaged in pre-approval promotion, we may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions.

Delays in clinical testing could result in increased costs to us.*

We may not be able to initiate or continue clinical studies or trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these clinical trials as required by the FDA or other regulatory authorities, whether due to the impacts of the ongoing COVID-19 pandemic or otherwise. Even if we are able to enroll a sufficient number of patients in our clinical trials, if the pace of enrollment is slower than we expect, the development costs for our product candidates may increase and the completion of our clinical trials may be delayed, or our clinical trials could become too expensive to complete. For example, for our Phase 3 clinical trial to further evaluate fostamatinib in hospitalized patients with COVID-19 is currently enrolling but may experience delays. Significant delays in clinical testing could negatively impact our product development costs and timing. Our estimates regarding timing are based on a number of assumptions, including assumptions based on past experience with our other clinical programs. If we are unable to enroll the patients in these trials at the projected rate, the completion of the clinical program could be delayed and the costs of conducting the program could increase, either of which could harm our business.

Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a study, delays from scaling up of a study, delays in reaching agreement on acceptable clinical trial agreement terms with prospective clinical sites, delays in obtaining institutional review board approval to conduct a study at a prospective clinical site or delays in recruiting subjects to participate in a study. In addition, we typically rely on third-party clinical investigators to conduct our clinical trials and other third-party organizations to oversee the operations of such trials and to perform data collection and analysis. The clinical investigators are not our employees, and we cannot control the amount or timing of resources that they devote to our programs. Failure of the third-party organizations to meet their obligations, whether due to the impacts of the ongoing COVID-19 pandemic or otherwise, could adversely affect clinical development of our products. As a result, we may face additional delaying factors outside our control if these parties do not perform their obligations in a timely fashion. For example, any number of those issues could arise with our clinical trials causing a delay. Delays of this sort could occur for the reasons identified above or other reasons. If we have delays in conducting the clinical trials or obtaining regulatory approvals, our product development costs will increase. For example, we may need to make additional payments to third-party investigators and organizations to retain their services or we may need to pay recruitment incentives. If the delays are significant, our financial results and the commercial prospects for our product candidates will be harmed, and our ability to become profitable will be delayed. Moreover, these third-party investigators and organizations may also have relationships with other commercial entities, some of which may compete with us. If these third-party investigators and organizations assist our competitors at our expense, it could harm our competitive position.

Due to the evolving effects of the COVID-19 pandemic, for several of our development programs, we are experiencing a disruption or delay in our ability to enroll and assess patients, maintain patient enrollment, supply study drug, report trial results, or interact with regulators, ethics committees or other important agencies due to limitations in employee resources or otherwise. In addition, some patients may not be able or willing to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 and adversely impact our clinical trial operations. In light of the evolving effects of the COVID-19 pandemic, we have taken, and will continue to take, measures to implement remote and virtual approaches to clinical development, including remote patient monitoring where possible, and if the COVID-19 pandemic continues and persists for an extended period of time, we could experience significant disruptions to our clinical development timelines, which would adversely affect our business, financial condition, results of operations and growth prospects.

We may not be able to obtain Emergency Use Authorization (EUA) for fostamatinib for the treatment of hospitalized patients with COVID-19, and, even if we do, absent supplemental NDA approval for that indication, such EUA would be revoked when the COVID-19 emergency terminates.*

Based on the results of the NIH/NHLBI-sponsored Phase 2 trial, in May 2021, we filed an EUA for the use of fostamatinib for the treatment of hospitalized patients with COVID-19. In August 2021, the FDA informed us that the clinical data submitted from the NIH/NHLBI-sponsored Phase 2 trial of fostamatinib to treat hospitalized patients suffering from COVID-19 was insufficient for EUA. We continue to focus on enrolling on our Rigel-led Phase 3 clinical trial, and we anticipate providing further safety and efficacy data from this larger trial of fostamatinib in COVID-19 patients. If this trial meets its endpoints, we plan to resubmit our EUA application with this additional data.

Section 564 of the FDCA allows the FDA to authorize the shipment of drugs, biological products, or medical devices that either lack required approval, licensure, or clearance (unapproved products), or are approved but are to be used for unapproved ways to diagnose, treat, or prevent serious diseases or conditions in the event of an emergency declaration by the HHS Secretary.

On February 4, 2020, then-HHS Secretary Alex M. Azar II declared a public health emergency for COVID-19, under 21 U.S.C. § 360bbb-3(b)(1), justifying the authorization of emergency use of unapproved therapeutic products, or unapproved uses of approved or cleared therapeutic products, to treat COVID-19. This determination was published in the Federal Register on February 7, 2020.

While this emergency declaration is effective, the FDA may authorize the use of an unapproved product or an unapproved use of an approved product if it concludes that:

- an agent referred to in the emergency declaration could cause a serious or life-threatening disease or condition;
- it is reasonable to believe that the authorized product may be effective in diagnosing, treating, or preventing that disease or condition or a serious or life-threatening disease or condition caused by an approved product or a product marketed under an EUA;
- the known and potential benefits of the authorized product, when used for that disease or condition, outweigh known and potential risks, taking into consideration the material threat of agents identified in the emergency declaration;
- there is no adequate, approved, and available alternative to the authorized product for diagnosing, preventing, or treating the relevant disease or condition;
- any other criteria prescribed by the FDA is satisfied.

Medical products that are granted an EUA are only permitted to commercialize their products under the terms and conditions provided in the authorization. The FDCA authorizes FDA to impose such conditions on an EUA as may be necessary to protect the public health. Consequently, postmarketing requirements will vary across EUAs. In addition, FDA has, on occasion, waived requirements for drugs marketed under an EUA.

Generally, EUAs for unapproved products or unapproved uses of approved products require that manufacturers distribute factsheets for healthcare providers, addressing significant known and potential benefits and risk, and the extent to which benefits and risks are unknown, and the fact that FDA has authorized emergency use; and, distribution of factsheets for recipients of the product, addressing significant known and potential benefits and risk, and the extent to which benefits and risks are unknown, the option to accept or refuse the product, the consequences of refusing, available alternatives, and the fact that FDA has authorized emergency use.

Generally, EUAs for unapproved products and, per FDA's discretion, EUAs for unapproved uses of approved products, include requirements for adverse event monitoring and reporting, and other recordkeeping and reporting requirements. Note, however, that approved products are already subject to equivalent requirements.

In addition, FDA may include various requirements in an EUA as a matter of discretion as deemed necessary to protect the public health, including restrictions on which entities may distribute the product, and how to perform distribution (including requiring that distribution be limited to government entities), restrictions on who may administer the product, requirements for collection and analysis of safety and effectiveness data, waivers of cGMP, and restrictions applicable to prescription drugs or restricted devices (including advertising and promotion restrictions).

The FDA may revoke an EUA when it isdetermined that the underlying health emergency no longer exists or warrants such authorization, if the conditions for the issuance of the EUA are no longer met, or if other circumstances make revocation appropriate to protect the public health or safety. We cannot predict how long, if ever, an EUA would remain in place.

We cannot predict with certainty whether the Phase 3 study will meet its primary endpoint, and we therefore cannot guarantee that we will submit a second application for an EUA for fostamatinib. Even if the Phase 3 study does meet its primary endpoint, we cannot predict whether FDA will grant an EUA for fostamatinib based on the study data. We also cannot predict how long, if ever, an EUA would remain in place.

Our COVID-19 product candidate may not be successfully protect against variants of the SARS-CoV-2 virus.*

As the pandemic has continued, the SARS-CoV-2 virus continues to evolve, and new strains of the virus or those that are already in circulation may prove more transmissible or cause more severe forms of COVID-19 disease than the predominant strains to date. There is a risk that any product candidates we develop will not be as effective against variant strains of the SARS-CoV-2 virus expressing variants of the spike protein, particularly strains with mutations in the receptor binding domain and N-terminal domain. Such failure could lead to significant reputational harm, in addition to adversely affecting our financial results.

Public perceptions of the risk-benefit balance for our COVID-19 product candidates may be affected by adverse events in clinical trials involving our product candidate or other COVID-19 treatments*

Negative perception of the efficacy, safety, or tolerability of any investigational medicines that we develop, or of other products similar to products we are developing, such as fostamatinib for the treatment of COVID-19, could adversely affect our ability to conduct our business, advance our investigational medicines, or obtain regulatory approvals.

Adverse events in clinical trials of our investigational medicines or in clinical trials of others developing similar products, including other COVID-19 treatments, could result in a decrease in the perceived benefit of one or more of our programs, increased regulatory scrutiny, decreased confidence by patients and clinical trial collaborators in our investigational medicines, and less demand for any product that we may develop. If and when they are used in clinical trials, our developmental candidates and investigational medicines could result in a greater quantity of reportable adverse events, including suspected unexpected serious adverse reactions, other reportable negative clinical outcomes, manufacturing reportable events or material clinical events that could lead to clinical delay or hold by the FDA or applicable regulatory authority or other clinical delays, any of which could negatively impact the perception of one or more of our programs, as well as our business as a whole. In addition, responses by U.S., state, or foreign governments to negative public perception may result in new legislation or regulations that could limit our ability to develop any investigational medicines or commercialize any approved products, obtain or maintain regulatory approval, or otherwise achieve profitability. More restrictive statutory regimes, government regulations, or negative public opinion would have an adverse effect on our business, financial condition, results of operations, and prospects and may delay or impair the development of our investigational medicines and commercialization of any approved products or demand for any products we may develop.

We lack the capability to manufacture compounds for clinical development and we intend to rely on third parties for commercial supply, manufacturing and distribution if any of our product candidates which receive regulatory approval and we may be unable to obtain required material or product in a timely manner, at an acceptable cost or at a quality level required to receive regulatory approval.*

We currently do not have the manufacturing capabilities or experience necessary to produce TAVALISSE or any product candidates for clinical trials, including fostamatinib in AIHA, our IRAK inhibitor program and our RIP1 inhibitor program. We currently use one manufacturer of fostamatinib. We do not currently have, nor do we plan to acquire the infrastructure or capability to supply, manufacture or distribute preclinical, clinical or commercial quantities of drug substances or products. For each clinical trial of our unpartnered product candidates, we rely on third-party manufacturers for the active pharmaceutical ingredients, as well as various manufacturers to manufacture starting components, excipients and formulated drug products. Our ability to develop our product candidates, and our ability to commercially supply our products will depend, in part, on our ability to successfully obtain the APIs and other substances and materials used in our product candidates from third parties and to have finished products manufactured by third parties in accordance with regulatory requirements and in sufficient quantities for preclinical and clinical testing and commercialization. If we fail to develop and maintain supply relationships with these third parties, we may be unable to continue to develop or commercialize our product candidates.

We rely and will continue to rely on certain third parties, including those located outside the U.S., as our limited source of the materials they supply or the finished products they manufacture. The drug substances and other materials used in our product candidates are currently available only from one or a limited number of suppliers or manufacturers and certain of our finished product candidates are manufactured by one or a limited number of contract manufacturers. Any of these existing suppliers or manufacturers may:

- fail to supply us with product on a timely basis or in the requested amount due to unexpected damage to or destruction of facilities or equipment or otherwise;
- fail to increase manufacturing capacity and produce drug product and components in larger quantities and at higher yields in a timely or cost-effective manner, or at all, to sufficiently meet our commercial needs;
- be unable to meet our production demands due to issues related to their reliance on sole-source suppliers and manufacturers;

- supply us with product that fails to meet regulatory requirements;
- become unavailable through business interruption or financial insolvency;
- lose regulatory status as an approved source;
- be unable or unwilling to renew current supply agreements when such agreements expire on a timely basis, on acceptable terms or at all; or
- discontinue production or manufacturing of necessary drug substances or products.

Our current and anticipated future dependence upon these third-party manufacturers may adversely affect our ability to develop and commercialize product candidates on a timely and competitive basis, which could have an adverse effect on sales, results of operations and financial condition. If we were required to transfer manufacturing processes to other third-party manufacturers and we were able to identify an alternative manufacturer, we would still need to satisfy various regulatory requirements. Satisfaction of these requirements could cause us to experience significant delays in receiving an adequate supply of our products and products in development and could be costly. Moreover, we may not be able to transfer processes that are proprietary to the manufacturer, if any. These manufacturers may not be able to produce material on a timely basis or manufacture material at the quality level or in the quantity required to meet our development timelines and applicable regulatory requirements and may also experience a shortage in qualified personnel, including due to the impacts of the COVID-19 pandemic. We may not be able to maintain or renew our existing third-party manufacturing arrangements, or enter into new arrangements, on acceptable terms, or at all. Our third-party manufacturers could terminate or decline to renew our manufacturing arrangements based on their own business priorities, at a time that is costly or inconvenient for us. If we are unable to contract for the production of materials in sufficient quantity and of sufficient quality on acceptable terms, our planned clinical trials may be significantly delayed. Manufacturing delays could postpone the filing of our IND applications and/or the initiation or completion of clinical trials that we have currently planned or may plan in the future.

Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration, the European Medicines Agency, national competent authorities in the EU and UK and other federal and state government and regulatory agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards and they may not be able to comply. Switching manufacturers may be difficult because the number of potential manufacturers is limited. It may be difficult or impossible for us to find a replacement manufacturer quickly on acceptable terms, or at all. Additionally, if we are required to enter into new supply arrangements, we may not be able to obtain approval from the FDA of any alternate supplier in a timely manner, or at all, which could delay or prevent the clinical development and commercialization of any related product candidates. Failure of our third-party manufacturers or us to comply with applicable regulations, whether due to the impacts of the ongoing COVID-19 pandemic or otherwise, could result in sanctions being imposed on us, including fines, civil penalties, delays in or failure to grant marketing approval of our product candidates, injunctions, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products and compounds, operating restrictions and criminal prosecutions, warning or similar letters or civil, criminal or administrative sanctions against the company, any of which could adversely affect our business.

Any product for which we have obtained regulatory approval, or for which we obtain approval in the future, is subject to, or will be subject to, extensive ongoing regulatory requirements by the FDA, EMA and other comparable regulatory authorities, and if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, we may be subject to penalties, we will be unable to generate revenue from the sale of such products, our potential for generating positive cash flow will be diminished, and the capital necessary to fund our operations will be increased.

In April 2018, the FDA had approved TAVALISSE for the treatment of adult patients with chronic ITP who have had insufficient response to previous treatment. We launched fostamatinib in the United States on our own in late May 2018. In January 2019, we entered into an exclusive commercialization license agreement with Grifols to commercialize fostamatinib for the treatment, palliation, or prevention of human diseases, including chronic or persistent immune ITP, AIHA, and IgAN in Europe and Turkey and in October 2018, we entered into an exclusive license and supply agreement with Kissei for the development and commercialization of fostamatinib in all indications in Japan,

China, Taiwan, and the Republic of Korea. In October 2019, we also entered into two exclusive license agreements with Medison to commercialize fostamatinib in all potential indications in Canada and Israel. Any product for which we have obtained regulatory approval, or for which we obtain regulatory approval in the future, along with the manufacturing processes and practices, post-approval clinical research, product labeling, advertising and promotional activities for such product, are subject to continual requirements of, and review by, the FDA, the EMA and other comparable international regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, current good manufacturing practices (cGMP) requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians, import and export requirements and recordkeeping. If we or our suppliers encounter manufacturing, quality or compliance difficulties with respect to TAVALISSE or any of our product candidates, when and if approved, whether due to the impacts of the ongoing COVID-19 pandemic (including as a result of disruptions of global shipping and the transport of products) or otherwise, we may be unable to obtain or maintain regulatory approval or meet commercial demand for such products, which could adversely affect our business, financial conditions, results of operations and growth prospects.

Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we will not be able to promote any products we develop for indications or uses for which they are not approved.

In addition, the FDA often requires post-marketing testing and surveillance to monitor the effects of products. The FDA, the EMA and other comparable international regulatory agencies may condition approval of our product candidates on the completion of such post-marketing clinical studies. These post-marketing studies may suggest that a product causes undesirable side effects or may present a risk to the patient. Additionally, the FDA may require Risk Evaluation and Mitigation Strategies (REMS) to help ensure that the benefits of the drug outweigh its risks. A REMS may be required to include various elements, such as a medication guide or patient package insert, a communication plan to educate healthcare providers of the drug’s risks, limitations on who may prescribe or dispense the drug, requirements that patients enroll in a registry or undergo certain health evaluations or other measures that the FDA deems necessary to ensure the safe use of the drug.

Discovery after approval of previously unknown problems with any of our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in actions such as:

- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on product manufacturing processes;
- restrictions on the marketing of a product;
- restrictions on product distribution;
- requirements to conduct post-marketing clinical trials;
- untitled or warning letters or other adverse publicity;
- withdrawal of products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- refusal to permit the import or export of our products;
- product seizure;
- fines, restitution or disgorgement of profits or revenue;
- refusal to allow us to enter into supply contracts, including government contracts;

- injunctions; or
- imposition of civil or criminal penalties.

If such regulatory actions are taken, the value of our company and our operating results will be adversely affected. Additionally, if the FDA, the EMA or any other comparable international regulatory agency withdraws its approval of a product that is or may be approved, we will be unable to generate revenue from the sale of that product in the relevant jurisdiction, our potential for generating positive cash flow will be diminished and the capital necessary to fund our operations will be increased. Accordingly, we continue to expend significant time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance, post-marketing studies and quality control.

If any of our third-party contractors fail to perform their responsibilities to comply with FDA rules and regulations, the marketing and sales of our products could be delayed and we may be subject to enforcement action, which could decrease our revenues.*

Conducting our business requires us to manage relationships with third-party contractors. As a result, our success depends partially on the success of these third parties in performing their responsibilities to comply with FDA rules and regulations. Although we pre-qualify our contractors and we believe that they are fully capable of performing their contractual obligations, we cannot directly control the adequacy and timeliness of the resources and expertise that they apply to these activities.

If any of our partners or contractors fail to perform their obligations in an adequate and timely manner, or fail to comply with the FDA's rules and regulations, then the marketing and sales of our products could be delayed. FDA may also take enforcement actions against us based on compliance issues identified with our contractors. If any of these events occur, we may incur significant liabilities, which could decrease our revenues. For example, sales and medical science liaison or MSL personnel, including contractors, must comply with FDA requirements for the advertisement and promotion of products.

Fast track designation by the FDA may not actually lead to a faster development or regulatory review or approval process and does not assure FDA approval of our product candidates.*

If a product candidate is intended for the treatment of a serious or life-threatening condition and the product candidate demonstrates the potential to address unmet medical need for this condition, the sponsor may apply for FDA fast track designation. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a fast track product has opportunities for more frequent interactions with the review team during product development, and the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

However, fast track designation does not change the standards for approval and does not ensure that the product candidate will receive marketing approval or that approval will be granted within any particular timeframe. As a result, while the FDA has granted fast track designation to TAVALISSE for the treatment of warm AIHA and/or we may seek and receive fast track designation for our future product candidates, we may not experience a faster development process, review or approval compared to conventional FDA procedures. In addition, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast track designation alone does not guarantee qualification for the FDA's priority review procedures.

If we are unable to obtain regulatory approval to market products in the United States and foreign jurisdictions, we will not be permitted to commercialize products we or our collaborative partners may develop.

We cannot predict whether regulatory clearance will be obtained for any product that we, or our collaborative partners, hope to develop. Satisfaction of regulatory requirements typically takes many years, is dependent upon the type, complexity and novelty of the product and requires the expenditure of substantial resources. Of particular significance to us are the requirements relating to research and development and testing.

Before commencing clinical trials in humans in the United States, we, or our collaborative partners, will need to

submit and receive approval from the FDA of an IND application. Clinical trials are subject to oversight by institutional review boards and the FDA and:

- must be conducted in conformance with the FDA's good clinical practices and other applicable regulations;
- must meet requirements for institutional review board oversight;
- must meet requirements for informed consent;
- are subject to continuing FDA and regulatory oversight;
- may require large numbers of test subjects; and
- may be suspended by us, our collaborators or the FDA at any time if it is believed that the subjects participating in these trials are being exposed to unacceptable health risks or if the FDA finds deficiencies in the IND or the conduct of these trials.

While we have stated that we intend to file additional INDs for future product candidates, this is only a statement of intent, and we may not be able to do so because we may not be able to identify potential product candidates. In addition, the FDA may not approve any IND we or our collaborative partners may submit in a timely manner, or at all.

Before receiving FDA approval to market a product, we must demonstrate with substantial clinical evidence that the product is safe and effective in the patient population and the indication that will be treated. Data obtained from preclinical and clinical activities are susceptible to varying interpretations that could delay, limit or prevent regulatory approvals. In addition, delays or rejections may be encountered based upon additional government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. Failure to comply with applicable FDA or other applicable regulatory requirements may result in criminal prosecution, civil penalties, recall or seizure of products, total or partial suspension of production or injunction, adverse publicity, as well as other regulatory action against our potential products or us. Additionally, we have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approval.

If regulatory approval of a product is granted, this approval will be limited to those indications or disease states and conditions for which the product is demonstrated through clinical trials to be safe and efficacious. We cannot assure you that any compound developed by us, alone or with others, will prove to be safe and efficacious in clinical trials and will meet all of the applicable regulatory requirements needed to receive marketing approval.

Outside the United States, our ability, or that of our collaborative partners, to market a product is contingent upon receiving a marketing authorization from the appropriate regulatory authorities. This foreign regulatory approval process typically includes all of the risks and costs associated with FDA approval described above and may also include additional risks and costs, such as the risk that such foreign regulatory authorities, which often have different regulatory and clinical trial requirements, interpretations and guidance from the FDA, may require additional clinical trials or results for approval of a product candidate, any of which could result in delays, significant additional costs or failure to obtain such regulatory approval. There can be no assurance, however, that we or our collaborative partners will not have to provide additional information or analysis, or conduct additional clinical trials, before receiving approval to market product candidates.

We may be unable to expand our product pipeline, which could limit our growth and revenue potential.

Our business is focused on the discovery, development and commercialization of novel small molecule drugs that significantly improve the lives of patients with hematologic disorders, cancer and rare immune diseases. In this regard, we are pursuing internal drug discovery efforts with the goal of identifying new product candidates to advance into clinical trials. Internal discovery efforts to identify new product candidates require substantial technical, financial and human resources. These internal discovery efforts may initially show promise in identifying potential product candidates, yet ultimately fail to yield product candidates for clinical development for a number of reasons. For example, potential product candidates may, on later stage clinical study, be shown to have inadequate efficacy, harmful side effects, suboptimal pharmaceutical profiles or other characteristics suggesting that they are unlikely to be commercially

viable products.

Apart from our internal discovery efforts, our strategy to expand our development pipeline is also dependent on our ability to successfully identify and acquire or in-license relevant product candidates. However, the in-licensing and acquisition of product candidates is a highly competitive area, and many other companies are pursuing the same or similar product candidates to those that we may consider attractive. In particular, larger companies with more well-established and diverse revenue streams may have a competitive advantage over us due to their size, financial resources and more extensive clinical development and commercialization capabilities. Furthermore, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We may also be unable to in-license or acquire additional relevant product candidates on acceptable terms that would allow us to realize an appropriate return on our investment. If we are unable to develop suitable product candidates through internal discovery efforts, whether due to the impacts of the ongoing COVID-19 pandemic or otherwise, or if we are unable to successfully obtain rights to additional suitable product candidates, our business and prospects for growth could suffer. Even if we succeed in our efforts to obtain rights to suitable product candidates, the competitive business environment may result in higher acquisition or licensing costs, and our investment in these potential products will remain subject to the inherent risks associated with the development and commercialization of new medicines. In certain circumstances, we may also be reliant on the licensor for the continued development of the in-licensed technology and their efforts to safeguard their underlying intellectual property.

With respect to acquisitions, we may not be able to integrate the target company successfully into our existing business, maintain the key business relationships of the target, or retain key personnel of an acquired business. Furthermore, we could assume unknown or contingent liabilities or incur unanticipated expenses. Any acquisitions or investments made by us also could result in our spending significant amounts, issuing dilutive securities, assuming or incurring significant debt obligations and contingent liabilities, incurring large one-time expenses and acquiring intangible assets that could result in significant future amortization expense and significant write-offs, any of which could harm our operating results.

We have obtained orphan drug designation from the FDA for fostamatinib for the treatment of ITP and wAIHA, but we may not be able to obtain or maintain orphan drug designation or exclusivity for fostamatinib for the treatment of ITP, wAIHA or our other product candidates, or we may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

We have obtained orphan drug designation in the United States for fostamatinib for the treatment of ITP and wAIHA. We may seek orphan drug designation for other product candidates in the future. Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biologic intended to treat a rare disease or condition, which is defined as one occurring in a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full NDA, to market the same drug for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity. At this time, we do not have nor will we seek to apply for orphan drug designation in the EU or the UK in the foreseeable future.

We cannot assure you that any future application for orphan drug designation with respect to any other product candidate will be granted. If we are unable to obtain orphan drug designation with respect to other product candidates in the United States, we will not be eligible to obtain the period of market exclusivity that could result from orphan drug designation or be afforded the financial incentives associated with orphan drug designation. Even though we have received orphan drug designation for fostamatinib for the treatment of ITP and wAIHA, we may not be the first to obtain marketing approval for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States for fostamatinib for the treatment of ITP, wAIHA or any future product candidate may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially

defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan product is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is safer, more effective, or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

Risks Related to Commercialization

Our prospects are highly dependent on our first commercial product, TAVALISSE. To the extent that the commercial success of TAVALISSE in the United States is diminished or is not commercially successful, our business, financial condition and results of operations may be adversely affected, and the price of our common stock may decline. *

TAVALISSE is our only drug that has been approved for sale in the United States and Europe for patients with chronic ITP. We are focusing a significant portion of our activities and resources on fostamatinib, and we believe our prospects are highly dependent on, and a significant portion of the value of our company relates to, our ability to sustain successful commercialization of TAVALISSE in the United States. We have entered into an exclusive commercialization agreement with Grifols to commercialize fostamatinib in Europe.

Sustained successful commercialization of TAVALISSE is subject to many risks and uncertainties, including the impact of the COVID-19 pandemic on the successful commercialization in the United States, as well as the successful commercialization efforts for TAVLESSE in Europe through our partner, Grifols. Prior to TAVALISSE, we have never, as an organization, launched or commercialized a product, and there is no guarantee that we will be able to continue to do so successfully with fostamatinib for its approved indication. In addition, our partner, Grifols, is responsible for the commercial launch of TAVLESSE in Europe. Although Grifols launched TAVLESSE in Germany and the UK in July 2020, and began commercializing TAVLESSE in France, Italy and Spain in September 2021, we cannot be certain if Grifols will be successful in launching TAVLESSE in additional territories in Europe that it may pursue, or continue to be successful in commercializing and marketing in any such regions. There are numerous examples of unsuccessful product launches and failures to meet high expectations of market potential, including by pharmaceutical companies with more experience and resources than us.

As we continue to build out our commercial team, there are many factors that could cause the commercialization of TAVALISSE to be unsuccessful, including a number of factors that are outside our control. The commercial success of TAVALISSE depends on the extent to which patients and physicians accept and adopt TAVALISSE for patients with chronic ITP who have had an insufficient response to a previous treatment. We also do not know how physicians, patients and payors will respond to our future price increases of TAVALISSE. Physicians may not prescribe TAVALISSE and patients may be unwilling to use TAVALISSE if coverage is not provided or reimbursement is inadequate to cover a significant portion of the cost. TAVALISSE competes, and may in the future compete, with currently existing therapies, including generic drugs, and products currently under development. Our competitors, particularly large pharmaceutical companies, may deploy more resources to market, sell and distribute their products. If our efforts are not appropriately resourced to adequately promote our products, the commercial potential of our sales may be diminished. Additionally, any negative development for fostamatinib in clinical development in additional indications, such as in the clinical trials of fostamatinib in COVID-19 patients, may adversely impact the commercial results and potential of fostamatinib. Thus, significant uncertainty remains regarding the commercial potential of fostamatinib.

Market acceptance of fostamatinib will depend on a number of factors, including:

- the timing of market introduction of the product as well as competitive products;
- the clinical indications for which the product is approved;
- acceptance by physicians, the medical community and patients of the product as a safe and effective treatment;
- impacts due to the evolving effects of the COVID-19 pandemic;

- the ability to distinguish safety and efficacy from existing, less expensive generic alternative therapies, if any;
- the convenience of prescribing, administrating and initiating patients on the product and the length of time the patient is on the product;
- the potential and perceived value and advantages of the product over alternative treatments;
- the cost of treatment in relation to alternative treatments, including any similar generic treatments;
- pricing and the availability of coverage and adequate reimbursement by third-party payors and government authorities;
- the prevalence and severity of adverse side effects; and
- the effectiveness of sales and marketing efforts.

If we are unable to sustain anticipated level of sales growth from TAVALISSE, or if we fail to achieve anticipated product royalties and collaboration milestones, we may need to reduce our operating expenses, access other sources of cash or otherwise modify our business plans, which could have a negative impact on our business, financial condition and results of operations. For example, during the first quarter of 2021, we experienced lower than anticipated sales of TAVALISSE due to continuing impacts of the COVID-19 pandemic as well as the typical first quarter reimbursement issues such as the resetting of co-pays and the Medicare donut hole, along with physician and patient access issues created by the COVID-19 pandemic. Incrementally, our net product sales were negatively impacted by the decrease in level of inventories remaining at our distribution channels.

We also may not be successful entering into arrangements with third parties to sell and market one or more of our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, including Kissei's development and commercialization of fostamatinib in all indications in Japan, China, Taiwan, and the Republic of Korea, Grifols' commercialization of fostamatinib in Europe and Turkey and Medison for future commercialization of fostamatinib in Canada and Israel. As a consequence of our license agreements with Kissei, Grifols and Medison, we rely heavily upon their regulatory, commercial, medical affairs, market access and other expertise and resources for commercialization of fostamatinib in their respective territories outside of the United States. We cannot control the amount of resources that our partners dedicate to the commercialization of fostamatinib, and our ability to generate revenues from the commercialization of fostamatinib by our partners depends on their ability to achieve market acceptance of fostamatinib in its approved indications in their respective territories.

Furthermore, foreign sales of fostamatinib by our partners could be adversely affected by the imposition of governmental controls, political and economic instability, outbreaks of pandemic diseases, such as the COVID-19 pandemic, trade restrictions or barriers and changes in tariffs, and escalating global trade and political tensions. For example, the ongoing COVID-19 pandemic has resulted in increased travel restrictions and extended shutdowns of certain businesses in the U.S. and around the world. If our collaborators are unable to successfully complete clinical trials, delay commercialization of fostamatinib or do not invest the resources necessary to successfully commercialize fostamatinib in international territories where it has been approved, this could reduce the amount of revenue we are due to receive under these license agreements, resulting in harm to our business and operations. If we do not establish and maintain sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

Even if we, or any of our collaborative partners, are able to continue to commercialize TAVALISSE or any product candidate that we, or they, develop, the product may become subject to unfavorable pricing regulations, third-party payor reimbursement practices or labeling restrictions, all of which may vary from country to country and any of which could harm our business.*

The commercial success of any product for which we have obtained regulatory approval, or for which we obtain regulatory approval in the future will depend substantially on the extent to which the costs of our product or product candidates are or will be paid by third-party payors, including government health care programs and private health insurers. There is a significant trend in the health care industry by public and private payers to contain or reduce their

costs, including by taking the following steps, among others: decreasing the portion of costs payers will cover, ceasing to provide full payment for certain products depending on outcomes or not covering certain products at all. If payers implement any of the foregoing with respect to our products, it would have an adverse impact on our revenue and results of operations. If coverage is not available, or reimbursement is limited, we, or any of our collaborative partners, may not be able to successfully commercialize TAVALISSE or any of our product candidates in some jurisdictions. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us, or any of our collaborative partners, to establish or maintain pricing sufficient to realize an adequate return on our or their investments. In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors; therefore, coverage and reimbursement levels for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that may require us to provide scientific, clinical or other support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved drugs. Marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed, which could delay market entry (or, if pricing is not approved, we may be unable to sell at all in a country where we have received regulatory approval for a product. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some countries, the proposed pricing for a drug must be approved before it may be lawfully marketed). In addition, authorities in some countries impose additional obligations, such as health technology assessments (HTAs), which assess the performance of a drug in comparison with its cost. The outcome of HTA assessments is judged on a national basis and some payers may not reimburse the use of our products or may reduce the rate of reimbursement for our products and as a result, revenue from such products may decrease.

In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we, or any of our collaborative partners, might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy time periods, which may negatively impact the revenues we are able to generate from the sale of the product in that country. In particular, we cannot predict to what extent the evolving effects of the COVID-19 pandemic, depending on its scale and duration, may continue to disrupt global healthcare systems and access to our products or result in a widespread loss of individual health insurance coverage due to unemployment, a shift from commercial payor coverage to government payor coverage, or an increase in demand for patient assistance and/or free drug programs, any of which would adversely affect access to and demand for our products and our net sales. Adverse pricing limitations may also hinder our ability or the ability of any future collaborators to recoup our or their investment in one or more product candidates, even if our product candidates obtain marketing approval. Further, even if favorable coverage and reimbursement status is attained for one or more products for which we or our collaborative partners receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Therefore, our ability, and the ability of any of our collaborative partners, to successfully commercialize TAVALISSE or any of our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors.

Additionally, the labeling ultimately approved for any of our product candidates for which we have or may obtain regulatory approval may include restrictions on their uses and may be subject to ongoing FDA or international regulatory authority requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, record-keeping and reporting of safety and other post-market information. If we or any of our collaborative partners do not timely obtain or comply with the labeling approval by the FDA or international regulatory authorities on any of our product candidates, it may delay or inhibit our ability to successfully commercialize our products and generate revenues.

If we are unable to successfully market and distribute TAVALISSE and retain experienced sales force, our business will be substantially harmed.*

We currently have limited experience in marketing and selling pharmaceutical products. As a result, we will be required to expend significant time and resources and continuously train our sales force to be credible, persuasive and

compliant with applicable laws in marketing TAVALISSE for patients with chronic ITP who have had an insufficient response to a previous treatment. In addition, we must continually train our sales force to ensure that an appropriate and compliant message about TAVALISSE is being delivered. If we are unable to effectively train our sales force and equip them with compliant and effective materials, including medical and sales literature to help them appropriately inform and educate health care providers regarding the potential benefits and proper administration of TAVALISSE, our efforts to successfully commercialize TAVALISSE could be put in jeopardy, which would negatively impact our ability to generate product revenues.

We have established our distribution, sales, marketing and market access capabilities, all of which will be necessary to successfully commercialize TAVALISSE. As a result, we will be required to expend significant time and resources to market, sell, and distribute TAVALISSE to hematologists and hematologists-oncologists. There is no guarantee that the marketing strategies including our virtual strategies in response to the restrictions and limitations resulting from the COVID-19 pandemic, or the distribution, sales, marketing and market access capabilities that we have developed will be successful. Particularly, we are dependent on third-party logistics, specialty pharmacies and distribution partners in the distribution of TAVALISSE. If they are unable to perform effectively or if they do not provide efficient distribution of the medicine to patients, our business may be harmed. In addition, we actively participate in medical conferences and exhibits, such as the American Society of Clinical Oncology (ASCO) and ASH Annual Meeting & Exposition that are significant opportunities for us to educate physicians and key opinion leaders about TAVALISSE. Due to the COVID-19 pandemic, ASCO was held virtually in 2021 and it is uncertain if the other key conferences will be held virtually, postponed or cancelled. Such disruptions may prevent us from effectively educating the prescribing physicians and key opinion leaders about TAVALISSE which would negatively impact utilization of TAVALISSE and our results of operations and growth prospects could be adversely affected.

Maintaining our sales, marketing, market access and product distribution capabilities requires significant resources, and there are numerous risks involved with managing our commercial team, including our potential inability to successfully train, retain and incentivize adequate numbers of qualified and effective sales and marketing personnel. We are also competing for talent with numerous commercial and pre-commercial-stage oncology-focused biotechnology companies seeking to build out their commercial organizations, as well as other large pharmaceutical organizations that have extensive, well-funded and more experienced sales and marketing operations, and we may be unable to maintain or adequately scale our commercial organization as a result of such competition. If we cannot maintain effective sales, marketing, market access and product distribution capabilities, whether as a result of the ongoing COVID-19 pandemic or otherwise, we may be unable to maximize the commercial potential of TAVALISSE. Also, to the extent that the commercial opportunities for TAVALISSE grow over time, we may not properly judge the requisite size and experience of our current commercialization teams or the level of distribution necessary to market and sell TAVALISSE, which could have an adverse impact on our business, financial condition and results of operations.

We might not be able to successfully develop or commercialize our product candidates if problems arise in the clinical testing and approval process.*

The activities associated with the research, development and commercialization of fostamatinib and other product candidates in our pipeline must undergo extensive clinical trials, which can take many years and require substantial expenditures, subject to extensive regulation by the FDA and other regulatory agencies in the U.S. and by comparable authorities in other countries. The process of obtaining regulatory approvals in the U.S. and other foreign jurisdictions is expensive, and lengthy, if approval is obtained at all.

Our clinical trials may fail to produce results satisfactory to the FDA or regulatory authorities in other jurisdictions. The regulatory process also requires preclinical testing, and data obtained from preclinical and clinical activities are susceptible to varying interpretations. The FDA has substantial discretion in the approval process and may refuse to approve any NDA or sNDA and decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. Varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of fostamatinib for any individual, additional indications.

Due to the ongoing COVID-19 pandemic, it is also possible that we could experience delays in the timing of our interactions with regulatory authorities due to absenteeism by governmental employees or the diversion of regulatory authority efforts and attention to approval of other therapeutics or other activities related to COVID-19, which could delay or limit our ability to make planned regulatory submissions or develop and commercialize our product candidates on anticipated timelines.

In addition, delays or rejections may be encountered based upon changes in regulatory policy for product approval during the period of product development and regulatory agency review, which may cause delays in the approval or rejection of an application for fostamatinib or for our other product candidates.

Commercialization of our product candidates depends upon successful completion of extensive preclinical studies and clinical trials to demonstrate their safety and efficacy for humans. Preclinical testing and clinical development are long, expensive and uncertain processes.

In connection with clinical trials of our product candidates, we may face the following risks among others:

- the product candidate may not prove to be effective;
- the product candidate may cause harmful side effects;
- the clinical results may not replicate the results of earlier, smaller trials;
- we or third parties with whom we collaborate, may be significantly impacted by the evolving impacts of the ongoing COVID-19 pandemic;
- we, or the FDA or similar foreign regulatory authorities, may delay, terminate or suspend the trials;
- our results may not be statistically significant;
- patient recruitment and enrollment may be slower than expected;
- patients may drop out of the trials or otherwise not enroll; and
- regulatory and clinical trial requirements, interpretations or guidance may change.

We do not know whether we will be permitted to undertake clinical trials of potential products beyond the trials already concluded and the trials currently in process. It will take us, or our collaborative partners several years to complete any such testing, and failure can occur at any stage of testing. Interim results of trials do not necessarily predict final results, and acceptable results in early trials may not be repeated in later trials. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in advanced clinical trials, even after achieving promising results in earlier trials.

General Risks

Our business is currently adversely affected and could be materially and adversely affected in the future by the evolving effects of the COVID-19 pandemic as a result of the current and potential future impacts on our sales force and commercialization efforts, supply chain, regulatory, clinical development and corporate development activities and other business operations, in addition to the impact of a global economic slowdown.*

The COVID-19 pandemic has resulted in extended travel and other restrictions in order to reduce the spread of the disease. Several states and counties across the country including California and the San Francisco Bay Area issued orders and restrictions, including directing individuals to shelter in place, prohibiting certain non-essential gatherings, directing businesses and governmental agencies to cease non-essential operations at physical locations and advising against non-essential travel. In response to these public health directives and orders, we previously implemented work-from-home policies for certain employees and closed our office in South San Francisco requiring most of our personnel, including our administrative employees, to work remotely, and restricted on-site access to only those personnel performing essential activities. Although we have recently initiated the first phase of our return-to-work initiatives, majority of our employees continue to work remotely. Our continued reliance on personnel working from home may negatively impact productivity, disrupt, delay, or otherwise adversely impact our business. In addition, with most of our employees continuing to work remotely, our exposure to cybersecurity risk has increased. This also creates data accessibility concerns and make us more susceptible to communication disruptions. Although most states and counties have since eased restrictions as the number of COVID-19 cases declined, the resurgence of COVID-19 cases, including the highly infectious Delta variant of the virus, could force states and counties to reinstate more severe restrictions to reduce the spread of the disease. The evolving effects of the COVID-19 pandemic and government measures taken in

response have had a significant impact, both direct and indirect, on businesses and commerce, as significant reductions in business related activities have occurred, supply chains have been disrupted, and manufacturing and clinical development activities have been curtailed or suspended.

Since the COVID-19 pandemic was declared, we continued to observe reduced patient-doctor interactions and our representatives have had fewer visits with health care providers, which negatively affected our product sales and may continue to negatively affect our product sales in the future. Physicians with practices severely impacted by the COVID-19 pandemic, and who currently prescribe TAVALISSE, may eventually decide to close their independent practices and join a larger medical organization with a practice that does not prescribe TAVALISSE. Additionally, commercial related activities, such as our marketing programs, speaker bureaus, and market access initiatives have been conducted virtually, delayed or cancelled as a result of the COVID-19 pandemic. Resources have been deployed to enable our field-based employees to continue to engage virtually with health care providers. Although these virtual engagements have enabled our field team to support existing prescribers, as well as partner with new prescribers to identify appropriate patients for TAVALISSE, we cannot rule out the future impact on our business if the pandemic continues for an extended period of time.

With respect to clinical development, we have taken, and continue to take, measures to implement remote and virtual approaches, including remote patient monitoring where possible per recent FDA guidance and working with our investigators for appropriate care of these patients in a safe manner consistent with agency guidelines. We have a number of ongoing clinical trials, one of which is a global Phase 3 clinical study in wAIHA. A number of our clinical trial investigators have paused, postponed or delayed new patient enrollment and restricted site visits of existing patients enrolled. Although some sites have resumed patient screening, the progress is slow, and we continue to experience delays in new patient enrollment. We are continuing to make decisions country-by-country to minimize risk to the patients and clinical trial sites. We also rely heavily on our clinical trial investigators to inform us of the best course of action with respect to resuming enrollment/screening, considering the ability of sites to ensure patient safety or data integrity. Patients already enrolled in our studies continue to receive study drug, and we remain focused on supporting our sites in providing care for these patients and providing continued investigational drug supply. We continue to experience slower than anticipated enrollment in some of our clinical trials, and at this time we cannot currently fully forecast the scope of impact that the COVID-19 pandemic may have overall on clinical study results, including the timing thereof, or our ability to continue to treat patients enrolled in our trials, enroll and assess new patients, supply study drug and obtain complete data points in accordance with study protoco. In addition, our partner, Kissei, is currently conducting a Phase 3 clinical trial for fostamatinib in ITP in Japan the timing and completion of which could be delayed due to the COVID-19 pandemic. The delays may potentially delay future royalties on sales, as well as, receipt of future potential milestones. At this time, however, we cannot fully forecast the scope of impact that the COVID-19 pandemic may have on our partnership with Kissei.

With respect to our supply chain, we currently do not anticipate significant disruption in the supply chain for our commercial product, TAVALISSE. However, we do not know the full extent of the impact on our supply chain if the COVID-19 pandemic continues and persists for an extended period of time. We currently rely on third parties to, among other things, manufacture and ship our commercial product, raw materials and product supply for our clinical trials, perform quality testing and supply other goods and services to help manage our commercial activities, our clinical trials and our operations in the ordinary course of business. We have engaged actively with various elements of our supply chain and distribution channel, including our customers, contract manufacturers, and logistics and transportation provider, to meet demand for TAVALISSE and to remain informed of any challenges within our supply chain. We continue to monitor demand, and intend to adapt our plans as needed to continue to drive our business and meet our obligations during the evolving COVID-19 pandemic. However, if the COVID-19 pandemic continues and persists for an extended period of time, we may face continued disruptions to our supply chain and operations, and associated delays in the manufacturing and supply of TAVALISSE. Such supply disruptions would adversely impact our ability to generate sales of and revenues from TAVALISSE and our business, financial condition, results of operations and growth prospects could be adversely affected.

The COVID-19 pandemic has similarly affected our collaboration and licensing partners for the commercialization of fostamatinib globally, as well as our ability to advance our various clinical stage programs. We do not yet know the full impact of such disruptions on our partners' ability to advance commercialization of fostamatinib in the market and the timing of enrollment and completion of various clinical trials being conducted by our collaboration

partners.

Health regulatory agencies globally may experience prolonged disruptions in their operations as a result of the COVID-19 pandemic. For example, in response to the COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products inspections of domestic manufacturing facilities through April 2020. On March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities and provided guidance regarding the conduct of clinical trials. On July 10, 2020, the FDA announced that it is working toward the goal of restarting on-site inspections it deems to be "mission critical." On August 19, 2020, the FDA published guidance clarifying how it intends to conduct inspections during the COVID-19 pandemic, including how it plans to determine which inspections are "mission critical." The Agency recently published an updated form of this guidance on May 17, 2021. Additionally, on April 14, 2021, the FDA issued a guidance document in which the FDA described its plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites. According to the guidance, the FDA intends to request such remote interactive evaluations in situations where an in-person inspection would not be prioritized, deemed mission-critical, or where direct inspection is otherwise limited by travel restrictions, but where the FDA determines that remote evaluation would still be appropriate. It is unclear how FDA's policies and guidance will impact any inspections of our facilities, including our clinical trial sites. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. It is unknown how long these disruptions could continue. Any de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially affect the completion of our clinical trials.

In addition, the evolving effects of the COVID-19 pandemic has already resulted in a significant disruption of global financial markets. If the disruption persists and deepens, we could experience an inability to access additional capital or we may not be able to meet the requirements under our credit facility with MidCap in order for us to draw Tranche 3 and/or Tranche 4, each of which is $20.0 million. We could also experience an impact on liquidity, which could in the future negatively affect our capacity for certain corporate development transactions or our ability to make other important, opportunistic investments. In addition, a recession or market correction resulting from the impact of the evolving effects of COVID-19 could materially affect our business and the value of our commonstock. While we expect the evolving effects of the COVID-19 pandemic to adversely affect our business operations and financial results, the extent of the impact on our ability to generate sales of and revenues from our approved products, our ability to continue to secure new collaborations and support existing collaboration efforts with our partners, our clinical development and regulatory efforts, our corporate development objectives and the value of and market for our common stock, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration and severity of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the U.S. and other countries, and the effectiveness of actions taken globally to contain and treat the disease. For example, if remote work policies for certain portions of our business, or that of our business partners, are continuously extended and become more restrictive, we may need to reassess our priorities and our corporate objectives. Given the global economic slowdown, the risks and uncertainties associated with the pandemic could adversely affect our business, financial condition, results of operations and growth prospects in the future periods. These evolving effects could adversely affect our business, financial condition, results of operations and growth prospects, as further described in the risks and uncertainties described elsewhere in this 'Risk Factors' section.

To the extent the evolving effects of the COVID-19 pandemic continues to adversely affect our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described elsewhere in this 'Risk Factors' section.

Shareholder activism could cause material disruption to our business.

Publicly traded companies have increasingly become subject to campaigns by activist investors advocating corporate actions such as actions related to environment, social and governance (ESG) matters, financial restructuring, increased borrowing, dividends, share repurchases or even sales of assets or the entire company. Responding to proxy contests and other actions by such activist investors or others in the future could be costly and time-consuming, disrupt our operations and divert the attention of our Board of Directors and senior management from the pursuit of our business strategies, which could adversely affect our results of operations and financial condition.

Anti-takeover provisions in our charter documents and under Delaware law may make an acquisition of us, which may be beneficial to our stockholders, more difficult.

Provisions of our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us, even if doing so would benefit our stockholders. These provisions:

- establish that members of the board of directors may be removed only for cause upon the affirmative vote of stockholders owning a majority of our capital stock;
- authorize the issuance of "blank check" preferred stock that could be issued by our board of directors to increase the number of outstanding shares and thwart a takeover attempt;
- limit who may call a special meeting of stockholders;
- prohibit stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings;
- provide for a board of directors with staggered terms; and
- provide that the authorized number of directors may be changed only by a resolution of our board of directors.

In addition, Section 203 of the Delaware General Corporation Law, which imposes certain restrictions relating to transactions with major stockholders, may discourage, delay or prevent a third party from acquiring us.

Increasing use of social media could give rise to liability and may harm our business.

We and our employees are increasingly utilizing social media tools and our website as a means of communication. Despite our efforts to monitor evolving social media communication guidelines and comply with applicable laws and regulations, there is risk that the unauthorized use of social media by us or our employees to communicate about our products or business, sharing of publications in unintended audiences in other jurisdictions, or any inadvertent promotional activity or disclosure of material, nonpublic information through these means, may cause us to be found in violation of applicable laws and regulations, which may give rise to liability and result in harm to our business. In addition, there is also risk of inappropriate disclosure of sensitive information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse impact on our business, financial condition and results of operations. Furthermore, negative posts or comments about us or our products on social media could seriously damage our reputation, brand image and goodwill.

Our research and development efforts will be seriously jeopardized if we are unable to attract and retain key employees and relationships.

Our success depends on the continued contributions of our principal management and scientific personnel and on our ability to develop and maintain important relationships with leading academic institutions, scientists and companies in the face of intense competition for such personnel. In particular, our research programs depend on our ability to attract and retain highly skilled chemists, other scientists, and development, regulatory and clinical personnel. If we lose the services of any of our key personnel, our research and development efforts could be seriously and adversely affected. Our employees can terminate their employment with us at any time.

Global economic conditions could adversely impact our business.

The U.S. government has indicated its intent to alter its approach to international trade policy and in some cases to renegotiate, or potentially terminate, certain existing bilateral or multi-lateral trade agreements and treaties with foreign countries. In addition, the U.S. government has initiated or is considering imposing tariffs on certain foreign goods. Related to this action, certain foreign governments, including China, have instituted or are considering imposing

tariffs on certain U.S. goods. It remains unclear what the U.S. Administration or foreign governments will or will not do with respect to tariffs or other international trade agreements and policies. A trade war or other governmental action related to tariffs or international trade agreements or policies has the potential to disrupt our research activities, affect our suppliers and/or the U.S. economy or certain sectors thereof and, thus, could adversely impact our businesses.

The transition away from the London Interbank Offered Rate (LIBOR) could affect the value of certain short-term investments, outstanding debt from our existing credit facility as well as our ability to draw additional funds from our credit facility.

The UK's Financial Conduct Authority, which regulates LIBOR, has announced plans to phase out the use of LIBOR by the end of 2021. We have certain short-term investments which includes financial instruments, as well an existing debt facility subject to LIBOR. There remains uncertainty regarding the future utilization of LIBOR and the nature of any replacement rate, and any potential effects of the transition away from LIBOR on certain instruments into which we may enter in the future are not known. The transition process may involve, among other things, increased volatility or illiquidity in markets for instruments that currently rely on LIBOR. The transition may also result in reductions in the value of certain instruments or the effectiveness of related transactions such as hedges, increased borrowing costs, uncertainty under applicable documentation, or difficult and costly consent processes. Any such effects of the transition away from LIBOR, as well as other unforeseen effects, result in expenses, difficulties, complications or delays in connection with future financing efforts, which could have an adverse impact on our business, financial condition and results of operations.

Our facilities are located near known earthquake fault zones, and the occurrence of an earthquake or other catastrophic disaster could cause damage to our facilities and equipment, which could require us to cease or curtail operations.

Our facilities are located in the San Francisco Bay Area near known earthquake fault zones and are vulnerable to significant damage from earthquakes. We are also vulnerable to damage from other types of disasters, including fires, floods, power loss, communications failures and similar events. If any disaster were to occur, our ability to operate our business at our facilities would be seriously, or potentially completely, impaired, and our research could be lost or destroyed. In addition, the unique nature of our research activities and of much of our equipment could make it difficult for us to recover from a disaster. The insurance we maintain may not be adequate to cover our losses resulting from disasters or other business interruptions.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

The exhibits listed on the accompanying index to exhibits are filed or incorporated by reference (as stated therein) as part of this Quarterly Report on Form 10-Q.

Exhibit Number	Description of Document
3.1	Amended and Restated Certificate of Incorporation. (1)
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation. (2)
3.3	Amended and Restated Bylaws. (3)
4.1	Form of warrant to purchase shares of common stock. (4)
4.2	Specimen Common Stock Certificate. (5)
4.3	Warrant issued to HCP BTC, LLC for the purchase of shares of common stock. (6)
10.1#	Rigel Pharmaceuticals, Inc. Inducement Plan, as amended
31.1#	Certification required by Rule 13a-14(a) or Rule 15d-14(a) of the Exchange Act.
31.2#	Certification required by Rule 13a-14(a) or Rule 15d-14(a) of the Exchange Act.
32.1*#	Certification required by Rule 13a-14(b) or Rule 15d-14(b) of the Exchange Act and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

Filed herewith

* *The certifications attached as Exhibit 32.1 accompany this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the registrant for purposes of Section 18 of the Exchange Act.*

(1) Filed as an exhibit to Rigel's Current Report on Form 8-K filed on May 29, 2012, and incorporated herein by reference.
(2) Filed as an exhibit to Rigel's Current Report on Form 8-K filed on May 18, 2018, and incorporated herein by reference.
(3) Filed as an exhibit to Rigel's Current Report on Form 8-K filed on February 2, 2007, and incorporated herein by reference.
(4) Filed as an exhibit to Rigel's Registration Statement on Form S-1 (No. 333-45864), filed on September 15, 2000, as amended, and incorporated herein by reference.
(5) Filed as an exhibit to Rigel's Current Report on Form 8-K filed on June 24, 2003, and incorporated herein by reference.
(6) Filed as an exhibit to Rigel's Quarterly Report on Form 10-Q for the quarter ended March 31, 2009, and incorporated herein by reference.

SIGNATURES

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

RIGEL PHARMACEUTICALS, INC.

By: /s/ RAUL R. RODRIGUEZ
Raul R. Rodriguez
Chief Executive Officer
(Principal Executive Officer)

Date: November 2, 2021

By: /s/ DEAN L. SCHORNO
Dean L. Schorno
Chief Financial Officer
(Principal Financial Officer)

Date: November 2, 2021

Rigel Pharmaceuticals, Inc.

Inducement Plan

Adopted by the Compensation Committee: October 10, 2016

Amended by the Compensation Committee: January 3, 2017

Amended by the Compensation Committee: August 16, 2017

Amended by the Compensation Committee: November 7, 2017

Amended by the Compensation Committee: December 23, 2017

Amended by the Compensation Committee: January 24, 2018

Amended by the Compensation Committee: August 19, 2020

Amended by the Compensation Committee: September 30, 2021

1. General.

(a) Eligible Stock Award Recipients. The only persons eligible to receive grants of Stock Awards under this Plan are individuals who satisfy the standards for inducement grants under NASDAQ Marketplace Rule 5635(c)(4) and the related guidance under NASDAQ IM 5635-1. A person who previously served as an Employee or Director will not be eligible to receive Stock Awards under the Plan, other than following a *bona fide* period of non-employment. Persons eligible to receive grants of Stock Awards under this Plan are referred to in this Plan as "***Eligible Employees***". These Stock Awards must be approved by either a majority of the Company's "***Independent Directors***" (as such term is defined in NASDAQ Listing Rule 5605(a)(2)) or the Company's compensation committee, provided such committee is comprised solely of Independent Directors (the "***Independent Compensation Committee***") in order to comply with the exemption from the stockholder approval requirement for "inducement grants" provided under Rule 5635(c)(4) of the NASDAQ Listing Rules. NASDAQ Marketplace Rule 5635(c)(4) and the related guidance under NASDAQ IM 5635-1 are referred to in this Plan as the "***Inducement Award Rules***".

(b) Available Awards. The Plan provides for the grant of Options and Restricted Stock Unit Awards . All Options will be Nonstatutory Stock Options. Awards intended to qualify as stockholder-approved performance based compensation for purposes of Section 162(m) of the Code may not be granted under this Plan.

(c) Purpose. This Plan, through the granting of Stock Awards, is intended to provide (i) an inducement material for certain individuals to enter into employment with the Company within the meaning of Rule 5635(c)(4) of the NASDAQ Listing Rules, (ii) incentives for such persons to exert maximum efforts for the success of the Company and any Affiliate and (iii) a means by which Eligible Employees may be given an opportunity to benefit from increases in value of the Common Stock through the granting of Stock Awards.

2. Administration.

(a) Administration by Board. The Board will administer the Plan, provided, however, that Stock Awards may only be granted by either (i) a majority of the Company's Independent Directors or (ii) the Independent Compensation Committee. Subject to those constraints and the other constraints of the Inducement Award Rules, the Board may delegate some of its powers of administration of the Plan to a Committee, as provided in Section 2(c).

(b) Powers of Board. The Board will have the power, subject to, and within the limitations of, the express provisions of the Plan and the Inducement Award Rules:

(i) To determine: (A) who will be granted Stock Awards; (B) when and how each Stock Award will be granted; (C) what type of Stock Award will be granted; (D) the provisions of each Stock Award (which need not be identical), including when a person will be permitted to exercise or otherwise receive cash or Common Stock under the Stock Award; (E) the number of shares of Common Stock subject to, or the cash value of, a Stock Award; and (F) the Fair Market Value applicable to a Stock Award; provided, however, that Stock Awards may only be granted by either (i) a majority of the Company's Independent Directors or (ii) the Independent Compensation Committee.

(ii) To construe and interpret the Plan and Stock Awards granted under it, and to establish, amend and revoke rules and regulations for administration of the Plan and Stock Awards. The Board, in the exercise of these powers, may correct any defect, omission or inconsistency in the Plan or in any Stock Award Agreement, in a manner and to the extent it will deem necessary or expedient to make the Plan or Stock Award fully effective.

(iii) To settle all controversies regarding the Plan and Stock Awards granted under it.

(iv) To accelerate, in whole or in part, the time at which a Stock Award may be exercised or vest (or at which cash or shares of Common Stock may be issued).

(v) To suspend or terminate the Plan at any time. Except as otherwise provided in the Plan or a Stock Award Agreement, suspension or termination of the Plan will not materially impair a Participant’s rights under his or her then-outstanding Stock Award without his or her written consent except as provided in subsection (viii) below.

(vi) To amend the Plan in any respect the Board deems necessary or advisable, including, without limitation, adopting amendments relating to nonqualified deferred compensation under Section 409A of the Code and/or making the Plan or Stock Awards granted under the Plan exempt from or compliant with the requirements for nonqualified deferred compensation under Section 409A of the Code, subject to the limitations, if any, of applicable law. If required by applicable law or listing requirements, and except as provided in Section 9(a) relating to Capitalization Adjustments, the Company will seek stockholder approval of any amendment of the Plan that (A) materially increases the number of shares of Common Stock available for issuance under the Plan, (B) materially expands the class of individuals eligible to receive Stock Awards under the Plan, (C) materially increases the benefits accruing to Participants under the Plan, (D) materially reduces the price at which shares of Common Stock may be issued or purchased under the Plan, (E) materially extends the term of the Plan, or (F) materially expands the types of Stock Awards available for issuance under the Plan. Except as otherwise provided in the Plan (including subsection (viii) below) or a Stock Award Agreement, no amendment of the Plan will materially impair a Participant’s rights under an outstanding Stock Award without the Participant’s written consent.

(vii) To submit any amendment to the Plan for stockholder approval, including, but not limited to, amendments to the Plan intended to satisfy the requirements of Rule 16b-3 of Exchange Act or any successor rule.

(viii) To approve forms of Stock Award Agreements for use under the Plan and to amend the terms of any one or more outstanding Stock Awards, including, but not limited to, amendments to provide terms more favorable to the Participant than previously provided in the Stock Award Agreement, subject to any specified limits in the Plan that are not subject to Board discretion. A Participant’s rights under any Stock Award will not be impaired by any such amendment unless the Company requests the consent of the affected Participant, and the Participant consents in writing. However, a Participant’s rights will not be deemed to have been impaired by any such amendment if the Board, in its sole discretion, determines that the amendment, taken as a whole, does not materially impair the Participant’s rights. In addition, subject to the limitations of applicable law, if any, the Board may amend the terms of any one or more Stock Awards without the affected Participant’s consent (A) to clarify the manner of exemption from, or to bring the Stock Award into compliance with, Section 409A of the Code, or (B) to comply with other applicable laws or listing requirements.

(ix) Generally, to exercise such powers and to perform such acts as the Board deems necessary or expedient to promote the best interests of the Company and that are not in conflict with the provisions of the Plan and/or Stock Award Agreements.

(x) To adopt such procedures and sub-plans as are necessary or appropriate (A) to permit participation in the Plan by individuals who are foreign nationals or employed outside the United States or (B) allow Stock Awards to qualify for special tax treatment in a foreign jurisdiction; *provided* that Board approval will not be necessary for immaterial modifications to the Plan or any Stock Award Agreement that are required for compliance with the laws of the relevant foreign jurisdiction.

(c) Delegation to Committee.

(i) General. The Board may delegate some or all of the administration of the Plan to a Committee or Committees. If administration of the Plan is delegated to a Committee, the Committee will have, in connection with the administration of the Plan, the powers theretofore possessed by the Board that have been delegated to the Committee, including the power to delegate to a subcommittee of the Committee any of the administrative powers the Committee is authorized to exercise (and references in this Plan to the Board will thereafter be to the Committee or subcommittee). Any delegation of administrative powers will be reflected in resolutions, not inconsistent with the provisions of the Plan, adopted from time to time by the Board or Committee (as applicable). The Committee may, at any time, abolish the subcommittee and/or revest in the Committee any powers delegated to the subcommittee. The Board may retain the authority to concurrently administer the Plan with the Committee and may, at any time, revest in the Board some or all of the powers previously delegated.

(ii) Rule 16b-3 Compliance. The Committee may consist solely of two or more Non-Employee Directors, in accordance with Rule 16b-3 of the Exchange Act.

(d) Effect of Board's Decision. All determinations, interpretations and constructions made by the Board in good faith will not be subject to review by any person and will be final, binding and conclusive on all persons.

(e) Cancellation and Re-Grant of Stock Awards. Neither the Board nor any Committee will have the authority to: (i) reduce the exercise, purchase or strike price of any outstanding Option, or (ii) cancel any outstanding Option that has an exercise price or strike price greater than the current Fair Market Value of the Common Stock in exchange for cash or other Stock Awards under the Plan, unless the stockholders of the Company have approved such an action within twelve (12) months prior to such an event.

3. Shares Subject to the Plan.

(a) Share Reserve .

(i) Subject to Section 9(a) relating to Capitalization Adjustments, the aggregate number of shares of Common Stock that may be issued pursuant to Stock Awards will not exceed 2,817,000 shares (the "***Share Reserve***").

(ii) Shares may be issued under the terms of this Plan in connection with a merger or acquisition as permitted by NASDAQ Listing Rule 5635(c), NYSE Listed Company Manual Section 303A.08, AMEX Company Guide Section 711 or other applicable rule, and such issuance will not reduce the number of shares available for issuance under the Plan.

(b) Reversion of Shares to the Share Reserve. If a Stock Award or any portion of a Stock Award (i) expires or otherwise terminates without all of the shares covered by the Stock Award having been issued or (ii) is settled in cash (*i.e.*, the Participant receives cash rather than stock), such expiration, termination or settlement will nevertheless reduce (or otherwise offset) the number of shares of Common Stock that are available for issuance under the Plan. If any shares of Common Stock issued under a Stock Award are forfeited back to or repurchased by the Company because of the failure to meet a contingency or condition required to vest such shares in the Participant, then the shares that are forfeited or repurchased will not revert to and again become available for issuance under the Plan.

Any shares reacquired by the Company in satisfaction of tax withholding obligations on a Stock Award or as consideration for the exercise or purchase price of a Stock Award will not again become available for issuance under the Plan.

(c) Source of Shares. The stock issuable under the Plan will be shares of authorized but unissued or reacquired Common Stock, including shares repurchased by the Company on the open market or otherwise.

4. Eligibility.

(a) Eligibility for Specific Stock Awards. Stock Awards may only be granted to persons who are Eligible Employees described in Section 1(a) of the Plan, where the Stock Award is an inducement material to the individual's entering into employment with the Company or an Affiliate within the meaning of Rule 5635(c)(4) of the NASDAQ Listing Rules, *provided however*, that Stock Awards may not be granted to Eligible Employees who are providing Continuous Service only to any "parent" of the Company, as such term is defined in Rule 405 of the Securities Act, unless (i) the stock underlying such Stock Awards is treated as "service recipient stock" under Section 409A of the Code (for example, because the Stock Awards are granted pursuant to a corporate transaction such as a spin off transaction), or (ii) the Company, in consultation with its legal counsel, has determined that such Stock Awards are otherwise exempt from or comply with the distribution requirements of Section 409A of the Code.

(b) Approval Requirements. All Stock Awards must be granted either by a majority of the Company's independent directors or the Independent Compensation Committee.

5. Provisions Relating to Options.

Each Option will be in such form and will contain such terms and conditions as the Board deems appropriate. All Options will be Nonstatutory Stock Options. The provisions of separate Options need not be identical; *provided, however*, that each Option Agreement will conform to (through incorporation of provisions hereof by reference in the applicable Option Agreement or otherwise) the substance of each of the following provisions:

(a) Term. No Option will be exercisable after the expiration of 10 years from the date of its grant or such shorter period specified in the Option Agreement.

(b) Exercise Price. The exercise or strike price of each Option will be not less than 100% of the Fair Market Value of the Common Stock subject to the Option on the date the Option is granted. Notwithstanding the foregoing, an Option may be granted with an exercise price lower than 100% of the Fair Market Value of the Common Stock subject to the Option if such Option is granted pursuant to an assumption of or substitution for another option or stock appreciation right pursuant to a Corporate Transaction and in a manner consistent with the provisions of Section 409A of the Code.

(c) Purchase Price for Options. The purchase price of Common Stock acquired pursuant to the exercise of an Option may be paid, to the extent permitted by applicable law and as determined by the Board in its sole discretion, by any combination of the methods of payment set forth below. The Board will have the authority to grant Options that do not permit all of the following methods of payment (or otherwise restrict the ability to use certain methods) and to grant Options that require the consent of the Company to use a particular method of payment. The permitted methods of payment are as follows:

(i) by cash, check, bank draft or money order payable to the Company;

(ii) pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of the stock subject to the Option, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the sales proceeds;

(iii) by delivery to the Company (either by actual delivery or attestation) of shares of Common Stock;

(iv) by a "net exercise" arrangement pursuant to which the Company will reduce the number of shares of Common Stock issuable upon exercise by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price; *provided, however*, that the Company will accept a cash or other payment from the Participant to the extent of any remaining balance of the aggregate exercise price not satisfied by such reduction in the number of whole shares to be issued. Shares of Common Stock will no longer be subject to an Option and will not be exercisable thereafter to the extent that (A) shares issuable upon exercise are used to pay the exercise price pursuant to the "net exercise," (B) shares are delivered to the Participant as a result of such exercise, and (C) shares are withheld to satisfy tax withholding obligations; or

(v) in any other form of legal consideration that may be acceptable to the Board and specified in the applicable Option Agreement.

(d) Transferability of Options. The Board may, in its sole discretion, impose such limitations on the transferability of Options as the Board will determine. In the absence of such a determination by the Board to the contrary, the following restrictions on the transferability of Options will apply:

(i) Restrictions on Transfer. An Option will not be transferable except by will or by the laws of descent and distribution (or pursuant to subsections (ii) and (iii) below), and will be exercisable during the lifetime of the Participant only by the Participant. The Board may permit transfer of the Option in a manner that is not prohibited by applicable tax and securities laws. Except as explicitly provided in the Plan, an Option may not be transferred for consideration.

(ii) Domestic Relations Orders. Subject to the approval of the Board or a duly authorized Officer, an Option may be transferred pursuant to the terms of a domestic relations order, official marital settlement agreement or other divorce or separation instrument.

(iii) Beneficiary Designation. Subject to the approval of the Board or a duly authorized Officer, a Participant may, by delivering written notice to the Company, in a form approved by the Company (or the designated broker), designate a third party who, on the death of the Participant, will thereafter be entitled to exercise the Option and receive the Common Stock or other consideration resulting from such exercise. In the absence of such a designation, the executor or administrator of the Participant's estate will be entitled to exercise the Option and receive the Common Stock or other consideration resulting from such exercise. However, the Company may prohibit designation of a beneficiary at any time, including due to any conclusion by the Company that such designation would be inconsistent with the provisions of applicable laws.

(e) Vesting Generally. The total number of shares of Common Stock subject to an Option may vest and therefore become exercisable in periodic installments that may or may not be equal. The Option may be subject to such other terms and conditions on the time or times when it may or may not be exercised (which may be based on the satisfaction of performance goals or other criteria) as the Board may deem appropriate. The vesting provisions of individual Options may vary. The provisions of this Section 5(e) are subject to any Option provisions governing the minimum number of shares of Common Stock as to which an Option may be exercised.

(f) Termination of Continuous Service. Except as otherwise provided in the applicable Option Agreement or other agreement between the Participant and the Company, if a Participant's Continuous Service terminates (other than for Cause and other than upon the Participant's death or Disability), the Participant may exercise his or her Option (to the extent that the Participant was entitled to exercise such Option as of the date of termination of Continuous Service) within the period of time ending on the earlier of (i) the date which occurs 3 months following the termination of the Participant's Continuous Service , and (ii) the expiration of the term of the Option as set forth in the Option Agreement. If, after termination of Continuous Service, the Participant does not exercise his or her Option within the applicable time frame, the Option will terminate.

(g) Extension of Termination Date. Except as otherwise provided in the applicable Stock Award Agreement, if the exercise of an Option following the termination of the Participant's Continuous Service (other than for Cause and other than upon the Participant's death or Disability) would be prohibited at any time solely because the issuance of shares of Common Stock would violate the registration requirements under the Securities Act, then the Option will terminate on the earlier of (i) the expiration of a total period of time (that need not be consecutive) equal to the applicable post-termination exercise period after the termination of the Participant's Continuous Service during which the exercise of the Option would not be in violation of such registration requirements, and (ii) the expiration of the term of the Option as set forth in the applicable Option Agreement. In addition, unless otherwise provided in a Participant's Option Agreement, if the sale of any Common Stock received upon exercise of an Option following the termination of the Participant's Continuous Service (other than for Cause) would violate the Company's insider trading policy, then the Option will terminate on the earlier of (i) the expiration of a period of days or months (that need not be consecutive) equal to the applicable post-termination exercise period after the termination of the Participant's Continuous Service during which the sale of the Common Stock received upon exercise of the Option would not be in violation of the Company's insider trading policy, or (ii) the expiration of the term of the Option as set forth in the applicable Option Agreement.

(h) Disability of Participant. Except as otherwise provided in the applicable Option Agreement or other agreement between the Participant and the Company, if a Participant's Continuous Service terminates as a result of the Participant's Disability, the Participant may exercise his or her Option (to the extent that the Participant was entitled to exercise such Option as of the date of termination of Continuous Service), but only within such period of time ending on the earlier of (i) the date 12 months following such te rmination of Continuous Service and (ii) the expiration of the term of the Option as set forth in the Option Agreement. If, after termination of Continuous Service, the Participant does not exercise his or her Option within the applicable time frame, the Option will terminate.

(i) Death of Participant. Except as otherwise provided in the applicable Option Agreement or other agreement between the Participant and the Company, if (i) a Participant's Continuous Service terminates as a result of the Participant's death, or (ii) the Participant dies within the period (if any) specified in the Option Agreement for exercisability after the termination of the Participant's Continuous Service for a reason other than death, then the Option may be exercised (to the extent the Participant was entitled to exercise such Option as of the date of death) by the Participant's estate, by a person who acquired the right to exercise the Option by bequest or inheritance or by a person designated to exercise the Option upon the Participant's death, but only within the period ending on the earlier of (i) the date 18 months following the date of death , and (ii) the expiration of the term of such Option as set forth in the Option Agreement. If, after the Participant's death, the Option is not exercised within the applicable time frame, the Option will terminate.

(j) Termination for Cause. Except as explicitly provided otherwise in a Participant's Stock Award Agreement or other individual written agreement between the Company or any Affiliate and the Participant, if a Participant's Continuous Service is terminated for Cause, the Option will terminate upon the date on which the event giving rise to the termination for Cause first occurred, and the Participant will be prohibited from exercising his or her Option from and after the date on which the event giving rise to the termination for Cause first occurred (or, if required by applicable law, the date of termination of Continuous Service). If a Participant's Continuous Service is suspended pending an investigation of the existence of Cause, all of the Participant's rights under the Option will also be suspended during the investigation period, except to the extent prohibited by applicable law.

(k) Non-Exempt Employees. If an Option is granted to an Employee who is a non-exempt employee for purposes of the Fair Labor Standards Act of 1938, as amended, the Option will not be first exercisable for any shares of Common Stock until at least 6 months following the date of grant of the Option (although the Option may vest prior to such date). Consistent with the provisions of the Worker Economic Opportunity Act, (i) if such non-exempt Employee dies or suffers a Disability, (ii) upon a Corporate Transaction in which such Option is not assumed, continued, or substituted, or (iii) upon the non-exempt Employee's retirement (as such term may be defined in the non-exempt Employee's Option Agreement in another agreement between the non-exempt Employee and the Company, or, if no such definition, in accordance with the Company's then current employment policies and guidelines), the vested portion of any Options may be exercised earlier than 6 months following the date of grant. The foregoing provision is intended to operate so that any income derived by a non-exempt employee in connection with the exercise or vesting of an Option will be exempt from his or her regular rate of pay. To the extent permitted and/or required for compliance with the Worker Economic Opportunity Act to ensure that any income derived by a non-

exempt Employee in connection with the exercise, vesting or issuance of any shares under any other Option will be exempt from such Employee's regular rate of pay, the provisions of this paragraph will apply to all Options and are hereby incorporated by reference into such Option Agreements.

6. Provisions Relating to Restricted Stock Unit Awards.

Each Restricted Stock Unit Award Agreement will be in such form and will contain such terms and conditions as the Board deems appropriate. The terms and conditions of Restricted Stock Unit Award Agreements may change from time to time, and the terms and conditions of separate Restricted Stock Unit Award Agreements need not be identical. Each Restricted Stock Unit Award Agreement will conform to (through incorporation of the provisions hereof by reference in the Agreement or otherwise) the substance of each of the following provisions:

(a) Consideration. At the time of grant of a Restricted Stock Unit Award, the Board will determine the consideration, if any, to be paid by the Participant upon delivery of each share of Common Stock subject to the Restricted Stock Unit Award. The consideration to be paid (if any) by the Participant for each share of Common Stock subject to a Restricted Stock Unit Award may be paid in any form of legal consideration that may be acceptable to the Board, in its sole discretion, and permissible under applicable law.

(b) Vesting. At the time of the grant of a Restricted Stock Unit Award, the Board may impose such restrictions on or conditions to the vesting of the Restricted Stock Unit Award as it, in its sole discretion, deems appropriate.

(c) Payment. A Restricted Stock Unit Award may be settled by the delivery of shares of Common Stock, their cash equivalent, any combination thereof or in any other form of consideration, as determined by the Board and contained in the Restricted Stock Unit Award Agreement.

(d) Additional Restrictions. At the time of the grant of a Restricted Stock Unit Award, the Board, as it deems appropriate, may impose such restrictions or conditions that delay the delivery of the shares of Common Stock (or their cash equivalent) subject to a Restricted Stock Unit Award to a time after the vesting of such Restricted Stock Unit Award.

(e) Dividend Equivalents. Dividend equivalents may be credited in respect of shares of Common Stock covered by a Restricted Stock Unit Award, as determined by the Board and contained in the Restricted Stock Unit Award Agreement. At the sole discretion of the Board, such dividend equivalents may be converted into additional shares of Common Stock covered by the Restricted Stock Unit Award in such manner as determined by the Board. Any additional shares covered by the Restricted Stock Unit Award credited by reason of such dividend equivalents will be subject to all of the same terms and conditions of the underlying Restricted Stock Unit Award Agreement to which they relate.

(f) Termination of Participant's Continuous Service. Except as otherwise provided in the applicable Restricted Stock Unit Award Agreement, such portion of the Restricted Stock Unit Award that has not vested will be forfeited upon the Participant's termination of Continuous Service.

7. Covenants of the Company.

(a) Availability of Shares. The Company will keep available at all times the number of shares of Common Stock reasonably required to satisfy then-outstanding Stock Awards.

(b) Securities Law Compliance. The Company will seek to obtain from each regulatory commission or agency having jurisdiction over the Plan such authority as may be required to grant Stock Awards and to issue and sell shares of Common Stock upon exercise of the Stock Awards; *provided, however,* that this undertaking will not require the Company to register under the Securities Act the Plan, any Stock Award or any Common Stock issued or issuable pursuant to any such Stock Award. If, after reasonable efforts and at a reasonable cost, the Company is unable to obtain from any such regulatory commission or agency the authority that counsel for the Company deems necessary for the lawful issuance and sale of Common Stock under the Plan, the Company will be relieved from any liability for

failure to issue and sell Common Stock upon exercise of such Stock Awards unless and until such authority is obtained. A Participant will not be eligible for the grant of a Stock Award or the subsequent issuance of cash or Common Stock pursuant to the Stock Award if such grant or issuance would be in violation of any applicable securities law.

(c) No Obligation to Notify or Minimize Taxes. The Company will have no duty or obligation to any Participant to advise such holder as to the time or manner of exercising such Stock Award. Furthermore, the Company will have no duty or obligation to warn or otherwise advise such holder of a pending termination or expiration of a Stock Award or a possible period in which the Stock Award may not be exercised. The Company has no duty or obligation to minimize the tax consequences of a Stock Award to the holder of such Stock Award.

8. Miscellaneous.

(a) Use of Proceeds from Sales of Common Stock. Proceeds from the sale of shares of Common Stock pursuant to Stock Awards will constitute general funds of the Company.

(b) Corporate Action Constituting Grant of Stock Awards. Corporate action constituting a grant by the Company of a Stock Award to any Participant will be deemed completed as of the date of such corporate action, unless otherwise determined by the Board, regardless of when the instrument, certificate, or letter evidencing the Stock Award is communicated to, or actually received or accepted by, the Participant. In the event that the corporate records (*e.g.*, Board consents, resolutions or minutes) documenting the corporate action constituting the grant contain terms (*e.g.*, exercise price, vesting schedule or number of shares) that are inconsistent with those in the Stock Award Agreement as a result of a clerical error in the papering of the Stock Award Agreement, the corporate records will control and the Participant will have no legally binding right to the incorrect term in the Stock Award Agreement.

(c) Stockholder Rights. No Participant will be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Common Stock subject to a Stock Award unless and until (i) such Participant has satisfied all requirements for exercise of, or the issuance of shares of Common Stock under, the Stock Award pursuant to its terms, and (ii) the issuance of the Common Stock subject to such Stock Award has been entered into the books and records of the Company.

(d) No Employment or Other Service Rights. Nothing in the Plan, any Stock Award Agreement or any other instrument executed thereunder or in connection with any Stock Award granted pursuant thereto will confer upon any Participant any right to continue to serve the Company or an Affiliate in the capacity in effect at the time the Stock Award was granted or will affect the right of the Company or an Affiliate to terminate (i) the employment of an Employee with or without notice and with or without cause, including, but not limited to, Cause, (ii) the service of a Consultant pursuant to the terms of such Consultant's agreement with the Company or an Affiliate, or (iii) the service of a Director pursuant to the bylaws of the Company or an Affiliate, and any applicable provisions of the corporate law of the state in which the Company or the Affiliate is incorporated, as the case may be.

(e) Change in Time Commitment. In the event a Participant's regular level of time commitment in the performance of his or her services for the Company and any Affiliates is reduced (for example, and without limitation, if the Participant is an Employee of the Company and the Employee has a change in status from a full-time Employee to a part-time Employee or takes an extended leave of absence) after the date of grant of any Stock Award to the Participant, the Board has the right in its sole discretion to (i) make a corresponding reduction in the number of shares or cash amount subject to any portion of such Stock Award that is scheduled to vest or become payable after the date of such change in time commitment, and (ii) in lieu of or in combination with such a reduction, extend the vesting or payment schedule applicable to such Stock Award. In the event of any such reduction, the Participant will have no right with respect to any portion of the Stock Award that is so reduced or extended.

(f) Investment Assurances. The Company may require a Participant, as a condition of exercising or acquiring Common Stock under any Stock Award, (i) to give written assurances satisfactory to the Company as to the Participant's knowledge and experience in financial and business matters and/or to employ a purchaser representative reasonably satisfactory to the Company who is knowledgeable and experienced in financial and business matters and that he or she is capable of evaluating, alone or together with the purchaser representative, the merits and risks of exercising the Stock Award, and (ii) to give written assurances satisfactory to the Company stating that the Participant is acquiring Common Stock subject to the Stock Award for the Participant's own account and not with any present

intention of selling or otherwise distributing the Common Stock. The foregoing requirements, and any assurances given pursuant to such requirements, will be inoperative if (i) the issuance of the shares upon the exercise of a Stock Award or acquisition of Common Stock under the Stock Award has been registered under a then currently effective registration statement under the Securities Act, or (ii) as to any particular requirement, a determination is made by counsel for the Company that such requirement need not be met in the circumstances under the then applicable securities laws. The Company may, upon advice of counsel to the Company, place legends on stock certificates issued under the Plan as such counsel deems necessary or appropriate in order to comply with applicable securities laws, including, but not limited to, legends restricting the transfer of the Common Stock.

(g) Withholding Obligations. Unless prohibited by the terms of a Stock Award Agreement, the Company may, in its sole discretion, satisfy any U.S. federal, state, local, foreign or other tax withholding obligation relating to a Stock Award by any of the following means or by a combination of such means: (i) causing the Participant to tender a cash payment; (ii) withholding shares of Common Stock from the shares of Common Stock issued or otherwise issuable to the Participant in connection with the Stock Award; *provided, however*, that no shares of Common Stock are withheld with a value exceeding the minimum amount of tax required to be withheld by law (or such other amount as may be necessary to avoid classification of the Stock Award as a liability for financial accounting purposes); (iii) withholding cash from a Stock Award settled in cash; (iv) withholding payment from any amounts otherwise payable to the Participant, including proceeds from the sale of shares of Common Stock issued pursuant to a Stock Award; or (v) by such other method as may be set forth in the Stock Award Agreement.

(h) Electronic Delivery. Any reference herein to a "written" agreement or document will include any agreement or document delivered electronically, filed publicly at www.sec.gov (or any successor website thereto), or posted on the Company's intranet (or other shared electronic medium controlled by the Company to which the Participant has access).

(i) Deferrals. To the extent permitted by applicable law, the Board, in its sole discretion, may determine that the delivery of Common Stock or the payment of cash, upon the exercise, vesting or settlement of all or a portion of any Stock Award may be deferred and may establish programs and procedures for deferral elections to be made by Participants. Deferrals by Participants will be made in accordance with Section 409A of the Code (to the extent applicable to a Participant). Consistent with Section 409A of the Code, the Board may provide for distributions while a Participant is still an employee or otherwise providing services to the Company. The Board is authorized to make deferrals of Stock Awards and determine when, and in what annual percentages, Participants may receive payments, including lump sum payments, following the Participant's termination of Continuous Service, and implement such other terms and conditions consistent with the provisions of the Plan and in accordance with applicable law.

(j) Compliance with Section 409A. Unless otherwise expressly provided for in a Stock Award Agreement and the Plan will be interpreted to the greatest extent possible in a manner that makes the Plan and the Stock Awards granted hereunder exempt from Section 409A of the Code, and, to the extent not so exempt, in compliance with Section 409A of the Code. If the Board determines that any Stock Award granted hereunder is not exempt from and is therefore subject to Section 409A of the Code, the Stock Award Agreement evidencing such Stock Award will incorporate the terms and conditions necessary to avoid the consequences specified in Section 409A(a)(1) of the Code, and to the extent a Stock Award Agreement is silent on terms necessary for compliance, such terms are hereby incorporated by reference into the Stock Award Agreement. Notwithstanding anything to the contrary in this Plan (and unless the Stock Award Agreement specifically provides otherwise), if the shares of Common Stock are publicly traded, and if a Participant holding a Stock Award that constitutes "deferred compensation" under Section 409A of the Code is a "specified employee" for purposes of Section 409A of the Code, no distribution or payment of any amount that is due because of a "separation from service" (as defined in Section 409A of the Code) will be issued or paid before the date that is six (6) months following the date of such Participant's "separation from service" or, if earlier, the date of the Participant's death, unless such distribution or payment can be made in a manner that complies with Section 409A of the Code, and any amounts so deferred will be paid in a lump sum on the day after such six (6) month period elapses, with the balance paid thereafter on the original schedule.

(k) Clawback/Recovery. All Stock Awards granted under the Plan will be subject to recoupment in accordance with any clawback policy that the Company is required to adopt pursuant to the listing standards of any national securities exchange or association on which the Company's securities are listed or as is otherwise required

by the Dodd-Frank Wall Street Reform and Consumer Protection Act or other applicable law. In addition, the Board may impose such other clawback, recovery or recoupment provisions in a Stock Award Agreement as the Board determines necessary or appropriate, including, but not limited to, a reacquisition right in respect of previously acquired shares of Common Stock or other cash or property upon the occurrence of an event constituting Cause. No recovery of compensation under such a clawback policy will be an event giving rise to a right to resign for "good reason" or "constructive termination" (or similar term) under any agreement with the Company or an Affiliate.

9. Adjustments upon Changes in Common Stock; Other Corporate Events.

(a) Capitalization Adjustments. In the event of a Capitalization Adjustment, the Board will appropriately and proportionately adjust: (i) the class(es) and maximum number of securities subject to the Plan pursuant to Section 3(a) and (ii) the class(es) and number of securities and price per share of stock subject to outstanding Stock Awards. The Board will make such adjustments, and its determination will be final, binding and conclusive.

(b) Dissolution or Liquidation. In the event of a dissolution or liquidation of the Company, then all outstanding Stock Awards shall terminate immediately prior to such event.

(c) Corporate Transaction. In the event of (i) a sale, lease or other disposition of all or substantially all of the securities or assets of the Company, (ii) a merger or consolidation in which the Company is not the surviving corporation or (iii) a reverse merger in which the Company is the surviving corporation but the shares of Common Stock outstanding immediately preceding the merger are converted by virtue of the merger into other property, whether in the form of securities, cash or otherwise (a "***Corporate Transaction***"), then any surviving corporation or acquiring corporation may assume any Stock Awards outstanding under the Plan or may substitute similar stock awards (including an award to acquire the same consideration paid to the stockholders in such Corporate Transaction) for those outstanding under the Plan. In the event any surviving corporation or acquiring corporation does not assume such Stock Awards or substitute similar stock awards for those outstanding under the Plan, then with respect to Stock Awards held by Participants whose Continuous Service has not terminated, the vesting of such Stock Awards (and, if applicable, the time during which such Stock Awards may be exercised) shall be accelerated in full, and the Stock Awards shall terminate if not exercised (if applicable) at or prior to such event. With respect to any other Stock Awards outstanding under the Plan, such Stock Awards shall terminate if not exercised (if applicable) prior to such event.

10. Termination or Suspension of the Plan.

The Board may suspend or terminate the Plan at any time. No Stock Awards may be granted under the Plan while the Plan is suspended or after it is terminated.

11. Effective Date of Plan; Timing of First Grant or Exercise.

The Plan will come into existence on the Effective Date. No Stock Award may be granted prior to the Effective Date.

12. Choice of Law.

The laws of the State of Delaware will govern all questions concerning the construction, validity and interpretation of this Plan, without regard to that state's conflict of laws rules.

13. Definitions. As used in the Plan, the following definitions will apply to the capitalized terms indicated below:

(a) "***Affiliate***" means, at the time of determination, any "parent" or "subsidiary" of the Company, as such terms are defined in Rule 405 of the Securities Act. The Board will have the authority to determine the time or times at which "parent" or "subsidiary" status is determined within the foregoing definition.

(b) "***Board***" means the Board of Directors of the Company.

(c) "***Capitalization Adjustment***" means any change that is made in, or other events that occur with respect to, the Common Stock subject to the Plan or subject to any Stock Award after the Effective Date without the receipt of consideration by the Company through merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, stock split, reverse stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or other similar equity restructuring transaction, as that term is used in Financial Accounting Standards Board Accounting Standards Codification Topic 718 (or any successor thereto). Notwithstanding the foregoing, the conversion of any convertible securities of the Company will not be treated as a Capitalization Adjustment.

(d) "***Cause***" will have the meaning ascribed to such term in any written agreement between the Participant and the Company or any Affiliate defining such term and, in the absence of such agreement, such term means, with respect to a Participant, the occurrence of any of the following events: (i) such Participant's conviction of any felony or any crime involving moral turpitude or dishonesty, (ii) such Participant's participation in a fraud or act of dishonesty against the Company, (iii) such Participant's conduct that, based upon a good faith and reasonable factual investigation and determination by the Board, demonstrates the Participant's gross unfitness to serve, or (iv) such Participant's intentional, material violation of any contract between the Company and the Participant or any statutory duty that the Participant has to the Company that the Participant does not correct within 30 days after written notice to the Participant thereof. The determination as to whether a Participant is being terminated for Cause will be made in good faith by the Company and will be final and binding on the Participant. Any determination by the Company that the Continuous Service of a Participant was terminated with or without Cause for the purposes of outstanding Stock Awards held by such Participant will have no effect upon any determination of the rights or obligations of the Company, any Affiliate or such Participant for any other purpose.

(e) "***Code***" means the U.S. Internal Revenue Code of 1986, as amended, including any applicable regulations and guidance thereunder.

(f) "***Committee***" means a committee of one (1) or more Independent Directors to whom authority has been delegated by the Board in accordance with Section 2(c).

(g) "***Common Stock***" means the common stock of the Company.

(h) "***Company***" means Rigel Pharmaceuticals, Inc., a Delaware corporation.

(i) "***Consultant***" means any person, including an advisor, who is (i) engaged by the Company or an Affiliate to render consulting or advisory services and is compensated for such services, or (ii) serving as a member of the board of directors of an Affiliate and is compensated for such services. However, service solely as a Director, or payment of a fee for such service, will not cause a Director to be considered a "Consultant" for purposes of the Plan. Notwithstanding the foregoing, a person is treated as a Consultant under this Plan only if a Form S-8 Registration Statement under the Securities Act is available to register either the offer or the sale of the Company's securities to such person.

(j) "***Continuous Service***" means that the Participant's service with the Company or an Affiliate, whether as an Employee, Director or Consultant, is not interrupted or terminated. A change in the capacity in which the Participant renders service to the Company or an Affiliate as an Employee, Consultant or Director or a change in the Entity for which the Participant renders such service, provided that there is no interruption or termination of the Participant's service with the Company or an Affiliate, will not terminate a Participant's Continuous Service. For example, a change in status from an Employee of the Company to a Consultant of an Affiliate or to a Director will not constitute an interruption of Continuous Service. If the Entity for which a Participant is rendering services ceases to qualify as an Affiliate, as determined by the Board in its sole discretion, such Participant's Continuous Service will be considered to have terminated on the date such Entity ceases to qualify as an Affiliate. To the extent permitted by law, the Board or the chief executive officer of the Company, in that party's sole discretion, may determine whether Continuous Service will be considered interrupted in the case of (i) any leave of absence approved by the Board or chief executive officer, including sick leave, military leave or any other personal leave, or (ii) transfers between the Company, an Affiliate, or their successors. In addition, if required for exemption from or compliance with Section 409A of the Code, the determination of whether there has been a termination of Continuous Service will be made, and such term will be construed, in a manner that is consistent with the definition of "separation from service" as defined

under Treasury Regulation Section 1.409A-1(h). A leave of absence will be treated as Continuous Service for purposes of vesting in a Stock Award only to such extent as may be provided in the Company's leave of absence policy, in the written terms of any leave of absence agreement or policy applicable to the Participant, or as otherwise required by law.

(k) "***Director***" means a member of the Board. Directors are not eligible to receive Stock Awards under the Plan with respect to their service in such capacity.

(l) "***Disability***" means the permanent and total disability of a person within the meaning of Section 22(e)(3) of the Code.

(m) "***Effective Date***" means October 10, 2016.

(n) "***Employee***" means any person employed by the Company or an Affiliate. However, service solely as a Director, or payment of a fee for such services, will not cause a Director to be considered an "Employee" for purposes of the Plan.

(o) "***Entity***" means a corporation, partnership, limited liability company or other entity.

(p) "***Exchange Act***" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

(q) "***Fair Market Value***" means, as of any date, the value of the Common Stock determined as follows:

(i) If the Common Stock is listed on any established stock exchange or traded on any established market, the Fair Market Value of a share of Common Stock will be, unless otherwise determined by the Board, the closing sales price for such stock as quoted on such exchange or market (or the exchange or market with the greatest volume of trading in the Common Stock) on the last market trading day prior to the date of determination, as reported in a source the Board deems reliable.

(ii) Unless otherwise provided by the Board, if there is no closing sales price for the Common Stock on the date of determination, then the Fair Market Value will be the closing selling price on the last preceding date for which such quotation exists.

(iii) In the absence of such markets for the Common Stock, the Fair Market Value will be determined by the Board in good faith and in a manner that complies with Section 409A of the Code.

(r) ***"Independent Director"*** has the meaning set forth in Section 1(a) above.

(s) "***Non-Employee Director***" means a Director who either (i) is not a current employee or officer of the Company or an Affiliate, does not receive compensation, either directly or indirectly, from the Company or an Affiliate for services rendered as a consultant or in any capacity other than as a Director (except for an amount as to which disclosure would not be required under Item 404(a) of Regulation S-K promulgated pursuant to the Securities Act ("***Regulation S-K***")), does not possess an interest in any other transaction for which disclosure would be required under Item 404(a) of Regulation S-K, and is not engaged in a business relationship for which disclosure would be required pursuant to Item 404(b) of Regulation S-K; or (ii) is otherwise considered a "non-employee director" for purposes of Rule 16b-3 of the Exchange Act.

(t) "***Nonstatutory Stock Option***" means any option granted pursuant to Section 4(b) of the Plan that does not qualify as an "incentive stock option" within the meaning of Section 422 of the Code.

(u) "***Officer***" means a person who is an officer of the Company within the meaning of Section 16 of the Exchange Act.

(v) "***Option***" means a Nonstatutory Stock Option to purchase shares of Common Stock granted pursuant to the Plan.

(w) "***Option Agreement***" means a written agreement between the Company and an Optionholder evidencing the terms and conditions of an Option grant. Each Option Agreement will be subject to the terms and conditions of the Plan.

(x) "***Optionholder***" means a person to whom an Option is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Option.

(y) "***Participant***" means a person to whom a Stock Award is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Stock Award.

(z) "***Plan***" means this Rigel Pharmaceuticals, Inc. Inducement Plan, as it may be amended.

(aa) "***Restricted Stock Unit Award***" means a right to receive shares of Common Stock which is granted pursuant to the terms and conditions of Section 6(b).

(bb) "***Restricted Stock Unit Award Agreement***" means a written agreement between the Company and a holder of a Restricted Stock Unit Award evidencing the terms and conditions of a Restricted Stock Unit Award grant. Each Restricted Stock Unit Award Agreement will be subject to the terms and conditions of the Plan.

(cc) ***"Rule 16b-3***" means Rule 16b-3 promulgated under the Exchange Act or any successor to Rule 16b-3, as in effect from time to time.

(dd) "***Securities Act***" means the Securities Act of 1933, as amended.

(ee) ***"Stock Award"*** means any right to receive Common Stock granted under the Plan, including an Option or a Restricted Stock Unit Award.

(ff) "***Stock Award Agreement*** " means a written agreement between the Company and a Participant evidencing the terms and conditions of a Stock Award grant. Each Stock Award Agreement will be subject to the terms and conditions of the Plan.

Exhibit 31.1

CERTIFICATIONS

I, Raul R. Rodriguez, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Rigel Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 2, 2021

/s/ RAUL R. RODRIGUEZ
Raul R. Rodriguez
Chief Executive Officer

Exhibit 31.2

CERTIFICATIONS

I, Dean L. Schorno, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Rigel Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 2, 2021

/s/ DEAN L. SCHORNO
Dean L. Schorno
Chief Financial Officer

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Raul R. Rodriguez, Chief Executive Officer of Rigel Pharmaceuticals, Inc. (the "Company"), and Dean L. Schorno, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2021, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

In Witness Whereof, the undersigned have set their hands hereto as of November 2, 2021.

/s/ RAUL R. RODRIGUEZ	/s/ DEAN L. SCHORNO
Raul R. Rodriguez	Dean L. Schorno
Chief Executive Officer	Chief Financial Officer

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Rigel Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.