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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, 2024

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.)
611 Gateway Boulevard, Suite 900, South San Francisco , CA	**94080**
(Address of principal executive offices)	(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 November 4, 2024, there were17,615,040 shares of the registrant's Common Stock outstanding.

RIGEL PHARMACEUTICALS, INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2024

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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

	As of	
	September 30, 2024	December 31, 2023 [1]
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 51,692	$ 32,786
Short-term investments	9,422	24,147
Accounts receivable, net	30,575	30,550
Inventories	4,784	5,522
Prepaid and other current assets	9,994	6,261
Total current assets	106,467	99,266
Property and equipment, net	99	165
Intangible assets, net	27,687	13,878
Operating lease right-of-use assets	405	861
Other assets	4,761	3,055
Total assets	$ 139,419	$ 117,225
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 3,815	$ 7,142
Accrued compensation	7,924	8,676
Accrued research and development	3,593	3,513
Acquisition-related liabilities	5,000	—
Revenue reserves and refund liability	22,192	15,684
Loans payable, net, current portion	—	7,229
Other accrued liabilities	9,967	5,334
Deferred revenue	1,355	1,355
Lease liabilities, current portion	466	692
Other long-term liabilities, current portion	—	3,642
Total current liabilities	54,312	53,267
Long-term portion of lease liabilities	—	285
Long-term portion of loans payable, net	59,762	52,373
Other long-term liabilities	39,981	39,944
Total liabilities	154,055	145,869
Commitments		
Stockholders' deficit:		
Common stock [2]	17	17
Additional paid-in capital [2]	1,389,742	1,378,881
Accumulated other comprehensive income	11	8
Accumulated deficit	(1,404,406)	(1,407,550)
Total stockholders' deficit	(14,636)	(28,644)
Total liabilities and stockholders' deficit	$ 139,419	$ 117,225

(1) The balance sheet as of December 31, 2023 has been derived from the audited financial statements included in Rigel's Annual Report on Form 10-K for the year ended December 31, 2023 filed with the Securities and Exchange Commission (SEC) on March 5, 2024.

(2) Common stock and additional paid-in capital have been restated to reflect the 1-for-10 reverse stock split effected on June 27, 2024 on a retroactive basis for the periods presented.

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,	
	2024	2023	2024	2023
Revenues:				
Product sales, net	$ 38,927	$ 27,129	$ 98,380	74,755
Contract revenues from collaborations	16,380	1,005	23,302	5,335
Government contracts	—	—	—	1,000
Total revenues	55,307	28,134	121,682	81,090
Costs and expenses:				
Cost of product sales	8,026	1,268	12,858	3,320
Research and development	6,182	6,475	17,748	21,336
Selling, general and administrative	27,043	24,856	83,539	78,891
Total costs and expenses	41,251	32,599	114,145	103,547
Income (loss) from operations	14,056	(4,465)	7,537	(22,457)
Interest income	425	672	1,570	1,594
Interest expense	(2,060)	(1,899)	(5,963)	(4,965)
Net income (loss)	$ 12,421	$ (5,692)	$ 3,144	$ (25,828)
Net income (loss) per share [1]				
Basic	$ 0.71	$ (0.33)	$ 0.18	$ (1.49)
Diluted	$ 0.70	$ (0.33)	$ 0.18	$ (1.49)
Weighted average shares used in computing net income (loss) per share [1]				
Basic	17,600	17,436	17,556	17,389
Diluted	17,648	17,436	17,599	17,389

(1) Share and per share amounts have been restated to reflect the 1-for-10 reverse stock split effected on June 27, 2024 on a retroactive basis for all periods presented.

See Accompanying Notes to Condensed Financial Statements

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Net income (loss)	$ 12,421	$ (5,692)	$ 3,144	(25,828)
Other comprehensive income:				
Net unrealized gain on short-term investments	20	10	3	138
Comprehensive income (loss)	$ 12,441	$ (5,682)	$ 3,147	$ (25,690)

See Accompanying Notes to Condensed Financial Statements

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

	Common Stock [1]		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital [1]	(Loss) Income	Deficit	Deficit
Balance as of January 1, 2024	17,482,513	$ 17	$ 1,378,881	$ 8	$(1,407,550)	$ (28,644)
Net loss	—	—	—	—	(8,247)	(8,247)
Net change in unrealized loss on short-term investments	—	—	—	(13)	—	(13)
Issuance of common stock upon exercise of options	9,066	—	89	—	—	89
Issuance of common stock upon vesting of restricted stock units (RSUs)	48,658	—	—	—	—	—
Stock-based compensation expense	—	—	5,144	—	—	5,144
Balance as of March 31, 2024	17,540,237	17	1,384,114	(5)	(1,415,797)	(31,671)
Net loss	—	—	—	—	(1,030)	(1,030)
Net change in unrealized loss on short-term investments	—	—	—	(4)	—	(4)
Issuance of common stock upon exercise of options and participation in Purchase Plan	36,130	—	252	—	—	252
Issuance of common stock upon vesting of RSUs	17,750	—	—	—	—	—
Stock-based compensation expense	—	—	2,539	—	—	2,539
Balance as of June 30, 2024	17,594,117	$ 17	$ 1,386,905	$ (9)	$(1,416,827)	$ (29,914)
Net income	—	—	—	—	12,421	12,421
Net change in unrealized gain on short-term investments	—	—	—	20	—	20
Issuance of common stock upon exercise of options	16,363	—	158	—	—	158
Issuance of common stock upon vesting of RSUs	2,500	—	—	—	—	—
Stock-based compensation expense	—		2,679	—	—	2,679
Balance as of September 30, 2024	17,612,980	$ 17	$ 1,389,742	$ 11	$(1,404,406)	$ (14,636)

	Common Stock [1]		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital [1]	(Loss)	Deficit	Deficit
Balance as of January 1, 2023	17,339,816	$ 17	$ 1,368,979	$ (153)	$(1,382,459)	$ (13,616)
Net loss	—	—	—	—	(13,536)	(13,536)
Net change in unrealized gain on short-term investments	—	—	—	126	—	126
Issuance of common stock upon exercise of options	95	—	1	—	—	1
Issuance of common stock upon vesting of RSUs	26,625	—	—	—	—	—
Stock-based compensation expense	—	—	2,768	—	—	2,768
Balance as of March 31, 2023	17,366,536	17	1,371,748	(27)	(1,395,995)	(24,257)
Net loss	—	—	—	—	(6,600)	(6,600)
Net change in unrealized gain on short-term investments	—	—	—	2	—	2
Issuance of common stock upon exercise of options and participation in Purchase Plan	52,379	—	554	—	—	554
Issuance of common stock upon vesting of RSUs	16,875	—	—	—	—	—
Stock-based compensation expense	—	—	2,186	—	—	2,186
Balance as of June 30, 2023	17,435,790	$ 17	$ 1,374,488	$ (25)	$(1,402,595)	$ (28,115)
Net loss	—	—	—	—	(5,692)	(5,692)
Net change in unrealized gain on short-term investments	—	—	—	10	—	10
Issuance of common stock upon exercise of options	883	—	8	—	—	8
Stock-based compensation expense	—	—	1,955	—	—	1,955
Balance as of September 30, 2023	17,436,673	$ 17	$ 1,376,451	$ (15)	$(1,408,287)	$ (31,834)

(1) All share amounts in this column, including appropriate reclassifications between common stock and additional paid-in capital, have been restated to reflect the 1-for-10 reverse stock split effected on June 27, 2024 on a retroactive basis for all periods presented.

See Accompanying Notes to Condensed Financial Statements

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

	Nine Months Ended September 30,	
	2024	**2023**
Operating activities		
Net income (loss)	$ 3,144	$ (25,828)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Stock-based compensation expense	10,306	6,873
(Gain) loss on sale and disposal of fixed assets	(23)	376
Depreciation and amortization	1,624	945
Net amortization of discount on short-term investments and term loans	(433)	(219)
Changes in assets and liabilities:		
Accounts receivable, net	(25)	16,774
Inventories	(1,161)	(1,359)
Prepaid and other current and non-current assets	(3,484)	5,329
Right-of-use assets	456	922
Accounts payable	(3,327)	491
Accrued compensation	(752)	(773)
Accrued research and development	80	(1,954)
Revenue reserves and refund liability	6,508	2,398
Other accrued liabilities	4,566	(1,455)
Lease liability	(511)	(966)
Deferred revenue	—	(14)
Other current and long-term liabilities	—	(1,043)
Net cash provided by operating activities	16,968	497
Investing activities		
Maturities of short-term investments	32,950	35,650
Purchases of short-term investments	(17,562)	(18,222)
Capital expenditures	(10)	—
Payments for acquisition of intangible assets	(360)	(15,000)
Proceeds from sale of property and equipment	26	149
Net cash provided by investing activities	15,044	2,577
Financing activities		
Net proceeds from term loan financing	—	19,950
Net proceeds from issuances of common stock upon exercise of options	499	563
Closing purchase price payment related to asset acquisition	(10,000)	—
Cost share payments to a collaboration partner	(3,605)	(2,632)
Net cash (used in) provided by financing activities	(13,106)	17,881
Net increase in cash and cash equivalents	18,906	20,955
Cash and cash equivalents at beginning of period	32,786	24,459
Cash and cash equivalents at end of period	$ 51,692	$ 45,414
Supplemental disclosure of cash flow information		
Interest paid	$ 5,292	$ 4,167
Acquisition-related liabilities	$ 5,000	$ —

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. Organization and Summary of Significant Accounting Policies

Description of Business

We are a biotechnology company dedicated to developing and providing novel therapies that significantly improve the lives of patients with hematologic disorders and cancer. We focus on products that address signaling pathways that are critical to disease mechanisms.

TAVALISSE® (fostamatinib disodium hexahydrate) is our first product approved by the US Food and Drug Administration (FDA). TAVALISSE is the only approved 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 and the United Kingdom (UK) (as TAVLESSE), and in Canada, Israel and Japan (as TAVALISSE) for the treatment of chronic ITP in adult patients.

REZLIDHIA® (olutasidenib) is our second FDA-approved product. REZLIDHIA capsules are indicated for the treatment of adult patients with relapsed or refractory (R/R) acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test. We in-licensed REZLIDHIA from Forma Therapeutics, Inc., now Novo Nordisk (Forma), with exclusive, worldwide rights for its development, manufacturing and commercialization.

GAVRETO® (pralsetinib) is our third FDA-approved product which we began commercializing on June 27, 2024. GAVRETO is a once daily, small molecule, oral, kinase inhibitor of wild-type rearranged during transfection (RET) and oncogenic RET fusions. GAVRETO is approved by the FDA for the treatment of adult patients with metastatic RET fusion-positive non-small cell lung cancer (NSCLC) as detected by an FDA-approved test. GAVRETO is also approved under accelerated approval based on overall response rate and duration response rate, for the treatment of adult and pediatric patients 12 years of age and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate). We acquired the rights to research, develop, manufacture and commercialize GAVRETO in the US from Blueprint Medicines Corporation (Blueprint) pursuant to an Asset Purchase Agreement entered in February 2024.

We continue to advance the development of R289, our dual interleukin receptor-associated kinases 1 and 4 (IRAK 1/4) inhibitor program, in an open-label, Phase 1b study to determine the tolerability and preliminary efficacy of the drug in patients with lower-risk myelodysplastic syndrome (MDS) who are relapsed, refractory or resistant to prior therapies.

We have strategic development collaborations with the University of Texas MD Anderson Cancer Center (MDACC) to expand our evaluation of olutasidenib in AML and other hematologic cancers with IDH1 mutations, and with Collaborative Network for Neuro-Oncology Clinical Trials (CONNECT) to conduct a Phase 2 clinical trial to evaluate olutasidenib in combination with temozolomide in patients with high-grade glioma (HGG) harboring an IDH1 mutation.

We have a receptor-interacting serine/threonine-protein kinase 1 (RIPK1) inhibitor program in clinical development with our partner Eli Lilly and Company (Lilly). We also have product candidates in clinical development with partners BerGenBio ASA (BerGenBio) and Daiichi Sankyo (Daiichi).

Reverse Stock Split

We filed with the Secretary of State of the State of Delaware a certificate of amendment to our Amended and Restated Certificate of Incorporation, to effect a 1-for-10 reverse stock split, effective June 27, 2024. As a result of the reverse stock split, every ten issued and outstanding shares of our common stock were automatically combined into one issued and outstanding share of common stock. Accordingly, an amount equal to the par value of the decreased shares resulting from the reverse stock split was reclassified from common stock to additional paid-in capital on the condensed balance sheet and statement of changes in stockholders' deficit. No fractional shares were issued in connection with the reverse stock split. Stockholders who otherwise would be entitled to receive fractional shares of common stock were entitled to receive the cash value equal to the fraction to which the stockholder would otherwise be entitled, multiplied by the closing price of the common stock as reported by Nasdaq on the last trading day prior to the effective date of the split. As a result of the reverse stock split, proportionate adjustments were made to the number of shares underlying (and as applicable, the exercise or conversion prices of) our outstanding equity awards and to the number of shares of common stock issuable under our equity incentive plans. The reverse stock split did not change the par value of our common stock, which remains $ 0.001 , or the authorized number of shares of our common stock. All share amounts and per share amounts disclosed in this Quarterly Report on Form 10-Q have been adjusted to reflect the reverse stock split on a retroactive basis for all periods presented.

Basis of Presentation

Our accompanying unaudited condensed financial statements have been prepared in accordance with United States generally accepted accounting principles (US 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 US 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, 2023 has been derived from audited financial statements at that date but does not include all disclosures required by US GAAP for complete financial statements. Because certain disclosures required by US 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, 2023.

Use of Estimates

The preparation of financial statements in conformity with US 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.

Significant Accounting Policies

Our significant accounting policies are described in "Note 1 – Description of Business and Summary of Significant Accounting Policies" to our "Notes to Financial Statements" contained in Part II, Item 8, "Financial Statements and Supplementary Data" of our Annual Report on Form 10-K for the year ended December 31, 2023. There have been no material changes to these accounting policies except for the accounting consideration related to the Asset Purchase Agreement with Blueprint as discussed below in "Note 5 – In-licensing and Acquisition."

Liquidity

As of September 30, 2024, we had approximately $ 61.1 million in cash, cash equivalents and short-term investments. We finance our operations primarily through sales of our products, and contract payments under our collaboration agreements, as well as through equity securities and debt financing.

Based on our current operating plan, we believe that our existing cash, cash equivalents, and short-term investments will be sufficient to fund our expenses and capital expenditure requirements for at least the next 12 months from the date of issuance of this Form 10-Q.

Recently Issued Accounting Standards

In November 2023, FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures.* This update expands public entities' segment disclosures, among others, requiring disclosure of significant segment expenses that are regularly provided to the chief operating decision maker and included within each reported measure of segment profit or loss; an amount and description of its composition for other segment items; and interim disclosures of a reportable segment's profit or loss and assets. All disclosure requirements under this update are also required for public entities with a single reportable segment. This update is effective for our Annual Report on Form 10-K for the fiscal year ending December 31, 2024, and interim periods thereafter. Early adoption is permitted. The update should be applied retrospectively to all periods presented in the financial statements. We are currently evaluating the impact of adopting this update on our financial statements and disclosures.

In December 2023, FASB issued ASU 2023-09, *Improvements to Income Tax Disclosures* , which enhance the annual disclosure requirements regarding the tax rate reconciliation and incomes taxes paid information. This update is effective for our fiscal year ending December 31, 2025, and maybe adopted on a prospective or retrospective basis. Early adoption is permitted. We are currently assessing the impact of adopting this guidance but do not expect it to have a significant impact to our financial statements and disclosures.

Other recently issued accounting guidance not discussed in this Quarterly Report on Form 10-Q are either not applicable or did not have, or are not expected to have, a material impact on us.

2. 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, RSUs and shares issuable under our Employee Stock Purchase Plan (Purchase Plan). The dilutive effect of these potentially dilutive securities is reflected in diluted earnings per share using 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,	
	2024	2023	2024	2023
EPS Numerator:				
Net income (loss)	$ 12,421	$ (5,692)	$ 3,144	$ (25,828)
EPS Denominator—Basic:				
Weighted-average common shares outstanding	17,600	17,436	17,556	17,389
EPS Denominator—Diluted:				
Weighted-average common shares outstanding	17,600	17,436	17,556	17,389
Dilutive effect of stock options, RSUs and shares under Purchase Plan	48	—	43	—
Weighted-average shares outstanding and common stock equivalents	17,648	17,436	17,599	17,389
Net income (loss) per share				
Basic	$ 0.71	$ (0.33)	$ 0.18	$ (1.49)
Diluted	$ 0.70	$ (0.33)	$ 0.18	$ (1.49)

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,	
	2024	2023	2024	2023
Stock options	3,667	3,428	3,668	3,428
RSUs	107	193	110	193
Shares under Purchase Plan	22	30	22	30
Total	3,796	3,651	3,800	3,651

3. Revenues

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Product sales:				
Gross product sales	$ 56,322	$ 38,585	$ 143,728	$ 105,239
Discounts and allowances	(17,395)	(11,456)	(45,348)	(30,484)
Total product sales, net	38,927	27,129	98,380	74,755
Revenues from collaborations:				
License revenue	10,000	—	10,000	—
Milestone revenue	—	75	—	75
Delivery of drug supplies, royalty and others	6,380	930	13,302	5,260
Total revenues from collaborations	16,380	1,005	23,302	5,335
Government contracts	—	—	—	1,000
Total revenues	$ 55,307	$ 28,134	$ 121,682	$ 81,090

Revenue from product sales are related to sales of our commercial products to our customers. For detailed discussions of our revenues from collaborations and government contracts, see “Note 4 – Sponsored Research, License Agreements and Government Contracts.”

Our net product sales include gross product sales, net of chargebacks, discounts and fees, government and other rebates and returns. Of the total discounts and allowances from gross product sales for the nine months ended September 30, 2024 and 2023, $ 44.6 million and $ 29.7 million, respectively, was accounted for as additions to revenue reserves and refund liability, and $ 0.7 million and $ 0.8 million, respectively, as reductions in accounts receivable (as it relates to allowance for prompt pay discount) and prepaid and other current assets (as it relates to certain chargebacks and other fees that were prepaid) in the condensed balance sheet. The following tables summarize the activities in chargebacks, discounts and fees, government and other rebates and returns that were accounted for within revenue reserves and refund liability, for each of the periods presented (in thousands):

	Chargebacks, Discounts and Fees	Government and Other Rebates	Returns	Total
Balance as of January 1, 2024	$ 8,236	$ 3,517	$ 3,931	$ 15,684
Provision related to current period sales	34,565	9,167	884	44,616
Credit or payments made during the period	(31,363)	(6,441)	(304)	(38,108)
Balance as of September 30, 2024	$ 11,438	$ 6,243	$ 4,511	$ 22,192

	Chargebacks, Discounts and Fees	Government and Other Rebates	Returns	Total
Balance as of January 1, 2023	$ 6,213	$ 2,636	$ 3,296	$ 12,145
Provision related to current period sales	23,150	5,932	623	29,705
Credit or payments made during the period	(21,504)	(5,631)	(172)	(27,307)
Balance as of September 30, 2023	$ 7,859	$ 2,937	$ 3,747	$ 14,543

The following table summarizes the percentages of revenues from each of our customers who individually accounted for 10% or more of the total net product sales and revenues from collaborations:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
McKesson Corporation	43 %	49 %	44 %	46 %
Cencora Inc. (formerly ASD Healthcare)	19 %	18 %	20 %	20 %
Cardinal Health, Inc.	*	28 %	15 %	27 %
Kissei	23 %	*	14 %	*

* Denotes less than 10%

4. Sponsored Research, License Agreements and Government Contracts

Sponsored Research and License Agreements

We conduct research and development programs independently and in connection with our corporate collaborators. As of September 30, 2024, we are a party to collaboration agreements with Lilly to develop and commercialize ocadusertib (previously R552), a RIPK1 inhibitor, for the treatment of non-central nervous system (non-CNS) diseases and collaboration aimed at developing additional RIPK1 inhibitors for the treatment of central nervous system (CNS) diseases; with Grifols S.A. (Grifols) to commercialize fostamatinib for human diseases in all indications in Grifols territory which includes Europe, the UK, Turkey, the Middle East, North Africa and Russia (including Commonwealth of Independent States); with Kissei Pharmaceutical Co., Ltd. (Kissei) to develop and commercialize fostamatinib in Japan, China, Taiwan and the Republic of Korea (Korea), and olutasidenib in Japan, Korea and Taiwan; 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, in Medison territory which includes Canada and Israel; and with Knight Therapeutics International SA (Knight) to commercialize fostamatinib in all indications, in Knight territory which includes Latin America, consisting of Mexico, Central and South America, and the Caribbean.

Further, we are also a party to collaboration agreements, but do not have ongoing performance obligations with BerGenBio for the development and commercialization of AXL receptor tyrosine kinase (AXL) inhibitors in oncology, and with Daiichi to pursue research related to murine double minute 2 (MDM2) inhibitors, a novel class of drug targets called ligases.

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. As of September 30, 2024, total future contingent payments to us under all of the above existing agreements, excluding terminated agreements, could exceed $ 1.4 billion if all potential product candidates achieved all of the payment triggering events under all of our current agreements. Of this amount, $ 279.5 million relates to the achievement of development events, $ 306.1 million relates to the achievement of regulatory events and $ 873.5 million relates to the achievement of certain commercial 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.

We account for the milestone payments when such 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 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.

Global Exclusive License Agreement with Lilly

We have a global exclusive license agreement and strategic collaboration with Lilly (Lilly Agreement) entered in February 2021, which became effective in March 2021, upon clearance under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, to develop and commercialize ocadusertib (previously R552) for the treatment of non-CNS diseases. In addition, the collaboration is aimed at developing additional RIPK1 inhibitors for the treatment of CNS diseases. Pursuant to the terms of the Lilly Agreement, we granted Lilly the exclusive rights to develop and commercialize ocadusertib and related RIPK1 inhibitors in all indications worldwide. The parties' collaboration is governed through a joint governance committee and appropriate subcommittees.

Under the terms of the Lilly 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. We are also entitled to additional milestone payments for non-CNS disease products consisting of up to $ 330.0 million in milestone payments upon the achievement of specified development, regulatory and commercial milestones, and up to $ 100.0 million in sales milestone payments on a product-by-product basis. In addition, depending on the extent of our co-funding of ocadusertib 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 are also eligible to receive milestone payments for CNS disease products consisting of up to $ 255.0 million in milestone payments upon the achievement of specified development, regulatory and commercial milestones, and up to $ 150.0 million in sales milestone payments on a product-by-product basis. 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.

Under the Lilly Agreement, we were responsible for performing and funding initial discovery and identification of CNS disease development candidates. Following candidate selection, Lilly is responsible for performing and funding all future development and commercialization of the CNS disease development candidates. Under the Lilly Agreement, we are responsible for 20 % of the development costs for ocadusertib in the US, Europe, and Japan, up to a specified cap, and Lilly is responsible for funding the remainder of all development activities for ocadusertib and other non-CNS disease development candidates. Pursuant to the terms of the Lilly Agreement, we have the right to opt-out of co-funding the ocadusertib development activities in the US, Europe and Japan at two different specified times and as a result receive lesser royalties from sales. Prior to us providing our first opt-out notice as discussed below, under the Lilly Agreement, we were required to fund our share of the ocadusertib development activities up to a maximum funding commitment of $ 65.0 million through April 1, 2024.

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 that 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.

At the inception of the Lilly Agreement, given our rights to opt-out from the development of ocadusertib, we believed at the minimum, we had 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 was accreted on such liability over the expected commitment period, adjusted for timing of expected cost share payments. No interest was accreted during the three and nine months ended September 30, 2024 and 2023.

At the inception, 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. The transaction price allocated to the non-CNS penetrant IP of $ 60.4 million was recognized as revenue upon delivery of the non-CNS penetrant IP to Lilly during the first quarter of 2021. The transaction price allocated to the CNS penetrant IP of $ 6.7 million was recognized as revenue from the effective date of the Lilly Agreement through the eventual acceptance by Lilly in June 2022 using the input method. There was no outstanding deferred revenue related to Lilly Agreement as of September 30, 2024 and December 31, 2023.

On September 28, 2023, we entered into an amendment to the Lilly Agreement which provides, among others that if we exercise our first opt-out right, we have the right to opt-in to the co-funding of ocadusertib development, upon us providing notice to Lilly within 30 days of certain events as specified in the Lilly Agreement, and as a result receive greater royalties from sales. Following the amendment to the Lilly Agreement, on September 29, 2023, we provided the first opt-out notice to Lilly, and our share on the ocadusertib development cost was capped to $ 22.6 million through April 1, 2024. If we exercise our opt-in right, we will be required to continue to share in global development costs, and if we later exercise our second opt-out right (no later than April 1, 2025), our share in global development costs will be up to a specified cap through December 31, 2025, as provided for in the Lilly Agreement.

Lilly billed us $ 21.4 million for our share of development costs incurred through April 1, 2024, and the amount was fully paid as of September 30, 2024. The outstanding liability to Lilly reported within other long-term liabilities (current and non-current) in the condensed balance sheets as of September 30, 2024 and December 31, 2023 amounted to $ 40.0 million and $ 43.6 million, respectively. As discussed above, following the amendment to the Lilly Agreement, and us providing the first opt-out notice to Lilly, our cost share obligation for ocadusertib development ended on April 1, 2024. Although currently we are no longer obligated to pay Lilly for our share in the ocadusertib development cost incurred subsequent to April 1, 2024, the outstanding liability reported in our condensed balance sheet as of September 30, 2024 amounting to $ 40.0 million has not been recognized as revenue because we cannot conclude that it is probable that a significant reversal of the amount of revenue, if recognized, will not occur until the likelihood of us exercising our opt-in right becomes remote, or when the opt-in right period lapses.

Grifols License Agreement

We have an exclusive commercialization license agreement with Grifols entered in January 2019 with exclusive rights to commercialize fostamatinib for human diseases, and non-exclusive rights to develop fostamatinib in Grifols territory. 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 are also entitled to receive stepped double-digit royalty payments based on tiered net sales which may reach 30 % of net sales. In January 2020, the European Commission (EC) granted a centralized Marketing Authorization (MA) for fostamatinib valid throughout the European Union (EU) and in the UK after the departure of the UK from the EU for the treatment of chronic ITP in adult patients who are refractory to other treatments. With this approval, in February 2020, we received $ 20.0 million non-refundable payment, composed of a $ 17.5 million payment due upon Marketing Authorization Application (MAA) approval by the European Medicines Agency (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. We accounted for this agreement under ASC 606, and recognized the corresponding revenue in the period we satisfied the performance obligations. There was no outstanding deferred revenue related to the Grifols license agreement as of September 30, 2024 and December 31, 2023.

We have a commercial supply agreement with Grifols entered in October 2020 to supply and sell our drug product priced at a certain markup specified in the agreement, in quantities Grifols order from us pursuant to and in accordance with the agreement. For the three and nine months ended September 30, 2024, we recognized $ 2.0 million of revenue related to the delivery of drug supply to Grifols. No revenue and $ 2.8 million of revenue was recognized for the three and nine months ended September 30, 2023, respectively, related to the delivery of drug supply to Grifols.

We recognized royalty revenue from Grifols of $ 1.3 million and $ 3.5 million for the three and nine months ended September 30, 2024, respectively, and $ 0.8 million and $ 2.3 million for the three and nine months ended September 30, 2023, respectively.

Kissei License Agreement – Olutasidenib

On September 3, 2024, we entered into a collaboration and license agreement with Kissei, pursuant to which Kissei was granted exclusive rights to develop and commercialize olutasidenib in all human diseases in Japan, Korea and Taiwan. Kissei is responsible for performing and funding the development activities for olutasidenib in the Kissei territory and we retained the co-exclusive right to conduct development activities in the Kissei territory solely for the purpose of supporting and obtaining regulatory approval of and commercializing olutasidenib in the world outside the Kissei territory. Under the terms of the agreement, we received a one-time, non-refundable, and non-creditable upfront cash payment of $ 10.0 million, with the potential for up to an additional $ 152.5 million in development, regulatory and commercial milestone payments, and will receive mid twenty to lower thirty percent, tiered, escalated net sales-based

payments for the supply of olutasidenib, subject to certain standard reductions and offsets . Pursuant to the agreement, Kissei is responsible for companion diagnostic development in Japan, for which we will share 50 % of the costs incurred by Kissei, up to $ 3.0 million, which are creditable against future milestones and transfer price payments owed to us. We remain responsible for the manufacture and supply of olutasidenib for all development and commercialization activities under the agreement. Pursuant to the concurrently executed supply agreement, we will supply Kissei with bulk drug product for use under the collaboration and license agreement.

We accounted for this agreement following ASC 606 and concluded at the inception of the agreement, the upfront cash payment of $ 10.0 million was the consideration for granting the license right to Kissei, and there are no other material deliverables associated with the upfront payment. Accordingly, we recognized the upfront payment as revenue during the three and nine months ended September 30, 2024. The variable considerations related to future development, regulatory and commercial milestones were fully constrained because it was probable that a significant reversal of cumulative revenue would occur, given the inherent uncertainty of success with these future milestones. We will re-evaluate the transaction price in each reporting period as uncertain events are resolved or other changes in circumstances occur. We will recognize revenues related to the supply of olutasidenib upon delivery and when we are entitled to receive the product transfer price payments.

Under the license and services agreement with Forma as discussed in “Note 5, In-licensing and Acquisition”, Forma is entitled to a certain portion of sublicensing revenue, which include, but are not limited to, upfront payments, milestone payments and royalties, that we receive from a third party sublicensee. Following the collaboration and license agreement with Kissei as discussed above, Forma is entitled to a portion of the sublicensing revenue we receive from Kissei. With the receipt of the upfront payment from Kissei, we recognized a $ 2.3 million sublicense revenue fee payable to Forma for the three and nine months ended September 30, 2024, which we recorded within cost of product sales. The amount was outstanding and recorded within other accrued liabilities in the condensed balance sheet as of September 30, 2024.

Kissei License Agreement – Fostamatinib

We have an exclusive license and supply agreement with Kissei entered in October 2018, amended in November 2022, October 2023, August 2024, and September 2024, to develop and commercialize fostamatinib in all current and potential indications in Japan, China, Taiwan and Korea. Kissei is responsible for performing and funding all development activities for fostamatinib in the above-mentioned territories. At the inception of the agreement, we received an upfront cash payment of $ 33.0 million. Further, the agreement provides for up to $ 115.0 million in potential development, regulatory and commercial milestone payments, and 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 Kissei’s territory 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. In April 2022, Kissei announced that an NDA was submitted to Japan’s Pharmaceuticals and Medical Devices Agency (PMDA) for fostamatinib in chronic ITP which entitled us to receive a $ 5.0 million non-refundable and non-creditable milestone payment. In December 2022, Kissei announced that Japan’s PMDA approved the NDA for fostamatinib in chronic ITP, which entitled us to receive a $ 20.0 million non-refundable and non-creditable milestone payment. We accounted for this agreement under ASC 606, and recognized the corresponding revenue in the period we satisfied the performance obligations. As of September 30, 2024 and December 31, 2023, the remaining deferred revenue was related to the material right associated with discounted fostamatinib supply which amounted to $ 1.4 million. No revenue was recognized during the three and nine months ended September 30, 2024 and 2023 associated with the remaining performance obligation.

For the three and nine months ended September 30, 2024, we recognized revenue from Kissei of $ 3.0 million and $ 7.5 million, respectively, related to the delivery of fosmatinib drug supply for commercial use. No such revenue was recognized during the three and nine months ended September 30, 2023.

Medison Commercial and License Agreements

We have exclusive commercial and license agreements with Medison entered in October 2019 for the commercialization of fostamatinib for chronic ITP in Medison territory, pursuant to which, we received a $ 5.0 million upfront payment with respect to the agreement in Canada. We accounted for this agreement 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. 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 auto immune hemolytic anemia in Canada. We determined that the non-refundable upfront fee represented the transaction price, however, due to the buyback provision, we accounted this upfront payment as financing arrangement under ASC 606. In 2022, management concluded that the likelihood of exercising the buyback option right was remote considering the top-line results from our Phase 3 trial of fostamatinib in warm auto immune hemolytic anemia (wAIHA) which showed that the trial did not demonstrate statistical significance in the primary efficacy endpoint, and the guidance received from the FDA. As such, in accordance with ASC 606, we relieved the outstanding financing liability which included the upfront payment and accreted interest, and recognized such amount as revenue in 2022. There was no outstanding deferred revenue related to Medison commercial and license agreement as of September 30, 2024 and December 31, 2023.

For the three and nine months ended September 30, 2024, we recognized revenue from Medison of $ 0.1 million and $ 0.2 million, respectively, related to the delivery of drug supply and earned royalties. For the three and nine months ended September 30, 2023, we recognized $ 0.2 million of revenue related to the delivery of drug supplies and a milestone pursuant to the commercial and license agreement.

Knight Commercial License and Supply Agreement

We have commercial license and supply agreements with Knight entered in May 2022 for the commercialization of fostamatinib for approved indications in Knight territory. Pursuant to such commercial license agreement, we received a $ 2.0 million one-time, non-refundable, and non-creditable upfront payment, with potential for up to an additional $ 20.0 million in regulatory and sales-based commercial milestone payments, and will receive twenty- to mid-thirty percent, tiered, escalated net-sales based royalty payments for products sold in the Knight territory. We accounted for this agreement under ASC 606 and identified that the upfront payment was a consideration for granting Knight the license to commercialize fostamatinib for approved indication in the Knight territory, and no further material deliverables associated to such upfront payment. As such, we recognized the upfront payment as revenue in 2022. We are also responsible for the exclusive manufacture and supply of fostamatinib for all future development and commercialization activities under the agreement.

Government Contracts

US Department of Defense (DOD)

Government contract revenue for the nine months ended September 30, 2023 of $ 1.0 million was from an award we received from DOD to support our Phase 3 clinical trial to evaluate the safety and efficacy of fostamatinib for the treatment of hospitalized high-risk patients with COVID-19. No revenue was recognized during the three and nine months ended September 30, 2024 and during the three months ended September 30, 2023 from this grant.

Biomedical Advanced Research and Development (BARDA)

In August 2023, we were awarded up to $ 0.8 million by BARDA, part of the Office of the Assistant Secretary for the Preparedness and Response at the US Department of Health and Human Services (DHHS), for our evaluation of fostamatinib in mitigating the impact of long-term respiratory distress. No revenue was recognized during the three and nine months ended September 30, 2024 and 2023 from this grant. Through September 30, 2024, we have received $ 0.1 million of the award.

Strategic Development Collaborations with MDACC and CONNECT

In December 2023, we entered into a Strategic Collaboration Agreement with MDACC, a comprehensive cancer research, treatment, and prevention center. The collaboration will expand our evaluation of olutasidenib in AML and other hematologic cancers. Under the collaboration, we will provide MDACC the study materials and $ 15.0 million in time-based milestone payments as compensation for services to be provided for the studies, over the five-year collaboration term, unless terminated earlier as provided for in the agreement. Through September 30, 2024, we provided $ 2.0 million funding to MDACC.

In January 2024, we announced our collaboration with CONNECT, an international collaborative network of pediatric cancer centers, to conduct a Phase 2 clinical trial to evaluate olutasidenib in glioma. Under the collaboration, we will provide funding up to $ 3.0 million and study material over the four-year collaboration.

We account for the funding we provide under the above research collaboration agreements as prepaid research and development in the balance sheet to the extent the payment is made in advance of services being rendered, and recognize such amount as research and development expense within the statements of operations as the collaborative partners render the services under the respective agreement.

5. In-licensing and Acquisition

Asset Purchase Agreement with Blueprint

On February 22, 2024, we acquired the US rights to research, develop, manufacture and commercialize GAVRETO (pralsetinib) from Blueprint pursuant to an Asset Purchase Agreement. The acquired assets include, among other things, applicable intellectual property related to pralsetinib in the US, including patents, copyrights and trademarks, as well as clinical regulatory and commercial data and records. Pursuant to the Asset Purchase Agreement, we agreed to pay a purchase price of $ 15.0 million, of which, $ 10.0 million was payable upon our first commercial sale of GAVRETO and an additional $ 5.0 million is payable on the first anniversary of the closing date of the agreement, subject to certain conditions. Blueprint is also eligible to receive up to $ 97.5 million in future commercial milestone payments and up to $ 5.0 million in future regulatory milestone payments. The potential regulatory milestones include full regulatory approval of pralsetinib (or related compounds) for the treatment of adult RET-fusion positive thyroid cancer, and maintenance of the current regulatory approval of pralsetinib for the treatment of adult RET-fusion positive thyroid cancer during the period beginning on February 22, 2024 and ending on the third anniversary of the first commercial sale of pralsetinib subject to certain conditions. Subject to the terms and conditions of the Asset Purchase Agreement, Blueprint would be entitled to tiered royalty payments on net sales of products containing pralsetinib (or related compounds) ranging from 10 % to 30 %, subject to certain reductions and offsets.

In accordance with ASC 805 *Business Combinations* (ASC 805), the transaction was accounted for as an asset acquisition, because substantially all of the fair value of the gross assets acquired is concentrated in a single asset, which is the GAVRETO product rights. The GAVRETO product rights comprised developed technology, customers, trademarks and trade name, and are considered a single asset as they are inextricably linked. ASC 805 provides for a screen test, wherein if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets, the assets acquired are not considered to be a business.

The following table summarizes the total purchase consideration in connection with the asset acquisition (in thousands):

Closing purchase price	$ 15,000
Transaction costs	360
Total purchase consideration	$ 15,360

$ 10.0 million of the closing purchase price was paid in July 2024, and the remaining $ 5.0 million is outstanding and presented as acquisition-related liabilities in the condensed balance sheet as of September 30, 2024. In accordance with the guidance, we classified the payment of the closing purchase price under financing activity in the condensed statements of cash flows, considering that the payment was not made soon after the acquisition date. The transaction

costs have been paid in cash as of September 30, 2024. The contingent considerations relating to future commercial and regulatory milestones were not included in the total purchase price consideration, and will be accounted for when the contingency is resolved and the consideration becomes payable. Royalties are recognized within cost of product sales, as revenue from GAVRETO product sales is recognized.

In an asset acquisition, the acquiring entity should recognize the assets acquired at cost to the acquiring entity which includes transaction costs and consideration given, allocated based on a relative fair value of the assets acquired measured at acquisition date. The fair value of the developed technology, customers, trademarks and trade name was estimated using a multi-period excess earnings income approach that discounts expected cash flows to present value by applying discount rate that represents the estimated rate that market participants would use to value such assets. The relative fair value are based on estimates that required judgement and certain assumptions, categorized as Level 3 in the fair value hierarchy. Since we acquired a single asset, the total purchase consideration was recorded as intangible assets. The related intangible assets is being amortized on a straight-line basis over the estimated useful life of 12 years , and the related amortization is recorded within cost of product sales.

Simultaneously and in connection with entering into the Asset Purchase Agreement, we also entered into certain supporting agreements, including a customary transition agreement, pursuant to which, during the transition period, Blueprint will transition regulatory and distribution responsibility for GAVRETO to us. We also agreed to purchase certain drug product inventories from Blueprint under a Material Transfer Agreement, and received such inventories amounting to approximately $ 6.5 million during the nine months ended September 30, 2024.

License and Transition Services Agreement with Forma

We have a license and transition services agreement with Forma entered in July 2022, for an exclusive license to develop, manufacture and commercialize olutasidenib, a proprietary inhibitor of mutated IDH1 (mIDH1), for any uses worldwide, including for the treatment of AML and other malignancies. Pursuant to the terms of the license and transition services agreement, we paid an upfront fee of $ 2.0 million, with the potential to pay up to $ 67.5 million of additional payments upon achievement of specified development and regulatory milestones and up to $ 165.5 million of additional payments upon achievement of certain commercial milestones. In addition, subject to the terms and conditions of the license and transition services agreement, Forma would be entitled to tiered royalty payments on net sales of licensed products at percentages ranging from low-teens to mid-thirties, as well as certain portion of our sublicensing revenue, subject to certain standard reductions and offsets.

The transaction was accounted for as an acquisition of asset under ASC 730, *Research and Development*. In accordance with the guidance, in a transaction accounted for as an asset acquisition, any acquired in-process research and development (IPR&D) that does not have alternative future use is charged to expense at the acquisition date. At the acquisition date, the acquired license asset was accounted for as IPR&D, and we anticipated no other economic benefit to be derived from such acquired licensed asset other than the primary indications. As such, we accounted for the upfront fee of $ 2.0 million as IPR&D and recorded such cost within research and development expense in the statements of operations in 2022.

Under the accounting guidance, we account for contingent payments when a contingency is resolved, and the consideration becomes payable. We account for milestone payment obligations incurred at development stage and prior to a regulatory approval of an indication associated with the acquired licensed asset as research and development expense when the event requiring payment of the milestone occurs. Milestone payment obligations incurred upon and after a regulatory approval of an indication associated with the acquired licensed asset, and at the commercial stage, are recorded as intangible assets when the event requiring payment of the milestones occurs. Prior to the FDA approval of REZLIDHIA in December 2022, a certain regulatory milestone was met which entitled Forma to receive a $ 2.5 million milestone payment. Because such milestone payment obligation was incurred prior to a regulatory approval of an indication associated with the acquired licensed asset, we recorded such amount as research and development expense in the fourth quarter of 2022. On December 1, 2022, the FDA approved REZLIDHIA capsules for the treatment of adult patients with R/R AML with susceptible IDH1 mutations as detected by an FDA-approved test. Following the FDA approval, we launched REZLIDHIA and made first shipments of the product to our customers in December 2022. With this FDA approval and first commercial sale of the product, Forma was entitled to receive a total of $ 15.0 million milestone payments. Since such milestone payment obligations were incurred upon and after regulatory approval of the

product, we recorded such amount as intangible assets on our condensed balance sheet in the fourth quarter of 2022. No new milestone was met in 2023 and during the nine months ended September 30, 2024.

The amount recorded as intangible asset is being amortized on a straight-line basis over the estimated useful life of 14 years , and the related amortization is recorded within cost of product sales. Royalties are recognized within cost of product sales, as revenue from REZLIDHIA product sales is recognized.

6. Stock-Based Compensation

Stock-based compensation for the periods presented was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Selling, general and administrative	$ 2,360	$ 1,596	$ 9,067	$ 5,127
Research and development	284	347	1,239	1,746
Total stock-based compensation expense	$ 2,644	$ 1,943	$ 10,306	$ 6,873

During the nine months ended September 30, 2024, we granted stock options to purchase 679,662 shares of common stock with weighted-average grant-date fair value of $ 9.36 per share, and 25,657 stock options were exercised. The stock options granted during the nine months ended September 30, 2024 generally vest over 3 years . As of September 30, 2024, there were 3,650,540 stock options outstanding, of which, 132,250 are outstanding performance-based stock options wherein the achievement of the corresponding corporate-based milestones were assessed not probable as of September 30, 2024. Accordingly, none of the $ 2.5 million grant date fair value for these awards has been recognized as stock-based compensation expense as of September 30, 2024.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model. The following table summarizes the weighted-average assumptions relating to options granted pursuant to our Equity Incentive Plans (our 2018 Equity Incentive Plan and Inducement Plan, as amended) for the periods presented:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Risk-free interest rate	3.8 %	4.3 %	4.1 %	3.8 %
Expected term (in years)	6.0	6.0	6.1	6.9
Dividend yield	0.0 %	0.0 %	0.0 %	0.0 %
Expected volatility	88.7 %	86.7 %	87.6 %	83.4 %

During the nine months ended September 30, 2024, we granted 291,373 RSUs with a grant-date weighted-average fair value of $ 12.52 per share, and 68,908 RSUs were released. The RSUs granted during the nine months ended September 30, 2024 generally vest over 3 years . As of September 30, 2024, there were 375,076 RSUs outstanding.

As of September 30, 2024, there was approximately $ 12.0 million of unrecognized stock-based compensation cost which is expected to be recognized over a remaining weighted-average period of 2.08 years, related to time-based stock options, performance-based stock options wherein achievement of the corresponding corporate-based milestones was considered as probable, and RSUs.

In March 2024, April 2024 and July 2024, our Board of Directors approved additional 158,122 shares of common stock reserved for issuance under our Inducement Plan. In May 2024, our stockholders approved an amendment to our 2018 Plan, to, among other items, add an additional 650,000 shares to the number of shares of common stock authorized for issuance under our 2018 Plan. As of September 30, 2024, there were 1,520,361 shares of common stock available for future grant under our Equity Incentive Plans.

Employee Stock Purchase Plan

Our Purchase Plan provides for a 24-month offering period comprises 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.

Our 24-month offering period under our Purchase Plan ended on June 30, 2024, and a new 24-month offering period started on July 1, 2024. The fair value of awards under our Purchase Plan is estimated on the date of our new offering period using the Black-Scholes option pricing model, which is being amortized over the requisite service periods. As of September 30, 2024, there was approximately $ 0.4 million of unrecognized stock-based compensation cost which is expected to be recognized over a remaining weighted-average period of 1.20 years, related to our Purchase Plan.

During the nine months ended September 30, 2024, there were 35,902 shares purchased under the Purchase Plan. As of September 30, 2024, there were 213,681 shares reserved for future issuance under the Purchase Plan.

7. Other Balance Sheet Components

Inventories

Inventories for the periods presented consist of the following (in thousands):

	As of	
	September 30, 2024	December 31, 2023
Raw materials	$ 1,569	$ 4,609
Work in process	1,811	1,876
Finished goods	5,830	1,508
Total	$ 9,210	$ 7,993
Reported as:		
Inventories	$ 4,784	$ 5,522
Other assets	4,426	2,471
Total	$ 9,210	$ 7,993

Inventories as of September 30, 2024 and December 31, 2023 include inventories acquired from Forma pursuant to the license and transition services agreement. Inventories as of September 30, 2024 also include inventories acquired from Blueprint pursuant to a Material Transfer Agreement as discussed in "Note 5 – In-licensing and Acquisition". As of September 30, 2024, advance payments to the manufacturer of our raw materials were included within prepaid and other current assets in the condensed balance sheet amounted to $ 3.4 million. No such advance payment was included within prepaid and other current assets as of December 31, 2023.

Non-current inventories consists of active pharmaceutical ingredients classified as raw materials which have multi-year shelf life, as well as certain work in process and finished goods inventories that are not expected to be consumed beyond our normal operating cycle.

Intangible assets

Intangible assets consist of the following (in thousands):

	As of	
	September 30, 2024	December 31, 2023
Intangible assets cost	$ 30,360	$ 15,000
Accumulated amortization	(2,673)	(1,122)
Intangible assets, net	$ 27,687	$ 13,878

See “Note 5 – In-licensing and Acquisition” for related discussions of capitalized intangible assets. Amortization expense recorded within cost of product sales in the condensed statements of operations for the three months ended September 30, 2024 and 2023 was $ 0.6 million and $ 0.3 million, respectively, and for the nine months ended September 30, 2024 and 2023 was $ 1.6 million and $ 0.8 million, respectively.

The following table presents the estimated future amortization expense of intangible assets as of September 30, 2024 (in thousands):

Remainder of 2024	$ 588
2025	2,351
2026	2,351
2027	2,351
2028	2,351
Thereafter	17,695
	$ 27,687

8. Cash, Cash Equivalents and Short-Term Investments

Cash, cash equivalents and short-term investments for the periods presented consist of the following (in thousands):

	As of	
	September 30, 2024	December 31, 2023
Cash	$ 25,853	$ 8,247
Money market funds	12,070	9,685
US treasury bills	6,980	12,594
Government-sponsored enterprise securities	8,484	11,233
Corporate bonds and commercial paper	7,727	15,174
	$ 61,114	$ 56,933
Reported as:		
Cash and cash equivalents	$ 51,692	$ 32,786
Short-term investments	9,422	24,147
	$ 61,114	$ 56,933

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

As of September 30, 2024	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
US treasury bills	$ 6,979	$ 1	$ —	$ 6,980
Government-sponsored enterprise securities	8,483	1	—	8,484
Corporate bonds and commercial paper	7,718	9	—	7,727
Total	$ 23,180	$ 11	$ —	$ 23,191

As of December 31, 2023	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
US treasury bills	$ 12,591	$ 3	$ —	$ 12,594
Government-sponsored enterprise securities	11,230	7	(4)	11,233
Corporate bonds and commercial paper	15,172	5	(3)	15,174
Total	$ 38,993	$ 15	$ (7)	$ 39,001

As of September 30, 2024 and December 31, 2023, our cash equivalents and short-term investments had a weighted-average time to maturity of approximately 39 days and 82 days , respectively. Our short-term investments are classified as available-for-sale securities. Accordingly, we have classified these securities as short-term investments on our condensed balance sheets as they are available for use in the current operations. As of September 30, 2024 and December 31, 2024, there were no individual securities that were in a significant unrealized loss position, and the individual securities with unrealized position have been in a loss position for less than one year. We regularly review the securities in an unrealized loss position and evaluate the current expected credit loss by considering factors such as historical experience, market data, issuer-specific factors, and current economic conditions. We have no t recognized any credit losses as of September 30, 2024 and December 31, 2023.

9. Fair Value

The table below summarizes the fair value of our cash equivalents and short-term investments measured at fair value on a recurring basis, and are categorized based upon the lowest level of significant input to the valuations (in thousands):

	Assets at Fair Value as of September 30, 2024			
	Level 1	Level 2	Level 3	Total
Money market funds	$ 12,070	$ —	$ —	$ 12,070
US treasury bills	—	6,980	—	6,980
Government-sponsored enterprise securities	—	8,484	—	8,484
Corporate bonds and commercial paper	—	7,727	—	7,727
Total	$ 12,070	$ 23,191	$ —	$ 35,261

	Assets at Fair Value as of December 31, 2023			
	Level 1	Level 2	Level 3	Total
Money market funds	$ 9,685	$ —	$ —	$ 9,685
US treasury bills	—	12,594	—	12,594
Government-sponsored enterprise securities	—	11,233	—	11,233
Corporate bonds and commercial paper	—	15,174	—	15,174
Total	$ 9,685	$ 39,001	$ —	$ 48,686

10. Debt

The following table summarizes loans payable, net (in thousands):

	As of	
	September 30, 2024	December 31, 2023
Principal outstanding	$ 60,000	$ 60,000
Unamortized debt issuance costs	(238)	(398)
Principal outstanding, net of unamortized debt issuance costs	$ 59,762	$ 59,602
Reported as:		
Loans payable, net, current portion	$ —	$ 7,229
Long-term portion of loans payable, net	59,762	52,373
	$ 59,762	$ 59,602

The outstanding loans payable as of the periods presented was related to our Credit and Security Agreement (Credit Agreement) with MidCap Financial Trust (MidCap) entered into on September 27, 2019 (Closing Date) and amended on March 29, 2021 (First Amendment), February 11, 2022 (Second Amendment), July 27, 2022 (Third Amendment), and on April 11, 2024 (Fourth Amendment).

The Credit Agreement provides for a $ 60.0 million term loan credit facility. At the Closing Date, $ 10.0 million was funded (Tranche 1), in May 2020, an additional $ 10.0 million was funded (Tranche 2), at the Second Amendment, an additional $ 10.0 million was funded (Tranche 3), at the Third Amendment, an additional $ 10.0 million was funded (Tranche 4), and in March 2023, an additional $ 20.0 million was funded (Tranche 5). As of September 30, 2024, no remaining funds were available for draw under the term loan credit facility.

The First Amendment to the Credit Agreement extended the period through which Tranche 3 was available to us. The Second Amendment to the Credit Agreement, among other things, amended the applicable funding conditions, applicable commitments and certain other terms relating to available credit facilities (Tranches 3 and 4), added additional term loan credit facility (Tranche 5), and revised certain terms related to the financial covenants.

Prior to the Fourth Amendment to the Credit Agreement as discussed below, the term loans would mature on September 1, 2026, and the interest-only period was through October 1, 2024. The term loans bore interest equal to the sum of one-month Secured Overnight Financing Rate (SOFR), plus an adjustment of 0.11448% , subject to 1.50 % applicable floor, plus applicable margin of 5.65 %, and a final payment fee of 2.5 % of principal due at maturity date.

Following the Fourth Amendment to the Credit Agreement, the term loans mature on September 1, 2027, and the interest-only period is through October 1, 2025. The term loans bear interest equal to the sum of one-month SOFR plus an adjustment of 0.11448% , subject to a 4.00 % applicable floor, plus applicable margin of 6.50 %. A final payment fee of 4.25 % of principal is due at maturity date. The amendment was accounted for as debt modification in accordance with the standards. The unamortized debt issuance costs are continuously being amortized as interest expense through maturity using the effective interest rate method.

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. The obligations under the amended Credit Agreement are secured by a perfected security interest in all of our assets including our intellectual property.

Interest expense, including amortization of the debt discount and accretion of the final fees related to the Credit Agreement for the three months ended September 30, 2024 and 2023 was $ 2.1 million and $ 1.9 million, respectively, and for the nine months ended September 30, 2024 and 2023 was $ 6.0 million and $ 5.0 million, respectively. Accrued interest of $ 1.9 million was included within other accrued liabilities in the condensed balance sheet as of September 30, 2024.

The following table presents the future minimum principal payments of the outstanding loan as of September 30, 2024 (in thousands):

Remainder of 2024	$	—
2025		7,500
2026		30,000
2027		22,500
Principal amount (Tranches 1, 2, 3 and 4)	$	60,000

The amended Credit Agreement contains certain covenants which, among others, require us to deliver financial reports at designated times of the year and maintain minimum unrestricted cash and trailing net revenues. As of September 30, 2024, we were not in violation of any covenants.

11. Leases

We have a sublease agreement with Atara Biotherapeutics, Inc. entered in October 2022 to sublease an office space located in South San Francisco, California. Subject to the terms of the sublease agreement, the lease term commenced in November 2022 and shall expire in May 2025. This leased facility is currently held as our Headquarters following the expiration of our previously leased facility in January 2023. The weighted average remaining term of our leases as of September 30, 2024 was 0.67 years.

We previously leased our prior headquarter space located in South San Francisco, California with Healthpeak Properties, Inc. (formerly known as HCP BTC, LLC), and had a sublease agreement with an unrelated third-party to sublet a portion of the leased facility. Both leases expired in January 2023.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Fixed operating lease expense	$ 166	$ 166	$ 498	944
Variable operating lease expense	28	75	84	105
Total operating lease expense	$ 194	$ 241	$ 582	$ 1,049

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Cash payments included in the measurement of operating lease liabilities	$ 184	$ 178	$ 552	1,352

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Fixed sublease expense	$ —	$ —	$ —	365
Variable sublease expense	—	—	—	77
Sublease income	—	—	—	(442)
Net	$ —	$ —	$ —	$ —

The following table presents the future lease payments as of September 30, 2024 (in thousands):

Remainder of 2024	$ 187
2025	301
Total minimum payments required	$ 488

12. Subsequent Event

Purchase commitment

In the ordinary course of business, we enter into agreements with contract manufacturers to manufacture our inventory products. In October 2024, we entered into an agreement with a third-party contract manufacturer to manufacture TAVALISSE that are expected to be delivered starting in fiscal year 2026 through 2029, for a total contract price of approximately $ 24.0 million. Although the agreement provides a cancellation clause with or without cause upon written notice, we may or may not be subject to payment of a cancellation fee. The level of cancellation fee is generally dependent on the timing of the written notice in relation to the commencement date of work, with the maximum cancellation fee equal to the full price of the work order.

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, 2023 filed with the SEC on March 5, 2024. Our financial results for the three and nine months ended September 30, 2024 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), and the Private Securities Litigation Reform Act of 1995, that involve risks and uncertainties. We usually use words such as "may," "will," "would," "should," "could," "expect," "plan," "anticipate," "might," "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: our business and scientific strategies; risks and uncertainties associated with the commercialization, distribution and marketing of our products in the US and outside the US; risks that the FDA, EMA, the Medicines and Health Products Regulatory Agency (MHRA) or other regulatory authorities may make adverse decisions regarding our products; 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 obligations to entities party to commercial or licensing agreements with us and the timing of those obligations; our expectations with respect to timing of recognizing product sales; our expectations with respect to regulatory submissions and approvals; our drug discovery technologies; our research and development expense; protection of our intellectual property and our intention to vigorously enforce our intellectual property rights; the availability and sufficiency of our cash and capital resources and the need for additional capital; our ability to successfully identify and acquire or in-license products or companies, and to successfully transition assets to operate acquisitions; our operations and legal risks; the effectiveness of our cybersecurity risk management process; and our acquisition of certain assets comprising rights to GAVRETO (pralsetinib) in the US. 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 developing and providing novel therapies that significantly improve the lives of patients with hematologic disorders and cancer. We focus on products that address signaling pathways that are critical to disease mechanisms.

TAVALISSE (fostamatinib disodium hexahydrate) is our first product approved by the FDA. TAVALISSE is the only approved oral SYK inhibitor for the treatment of adult patients with chronic ITP who have had an insufficient response to a previous treatment. The product is also commercially available in Europe and the UK (as TAVLESSE), and in Canada, Israel and Japan (as TAVALISSE) for the treatment of chronic ITP in adult patients.

REZLIDHIA (olutasidenib) is our second FDA-approved product. REZLIDHIA capsules are indicated for the treatment of adult patients with R/R AML with a susceptible IDH1 mutation as detected by an FDA-approved test. We in-licensed REZLIDHIA from Forma with exclusive, worldwide rights for its development, manufacturing and commercialization.

GAVRETO (pralsetinib) is our third FDA-approved product which we began commercializing on June 27, 2024. GAVRETO is a once daily, small molecule, oral, kinase inhibitor of wild-type RET and oncogenic RET fusions. GAVRETO is approved by the FDA for the treatment of adult patients with metastatic RET fusion-positive NSCLC as detected by an FDA-approved test. GAVRETO is also approved under accelerated approval based on overall response rate and duration response rate, for the treatment of adult and pediatric patients 12 years of age and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate). We acquired the rights to research, develop, manufacture and commercialize GAVRETO in the US from Blueprint pursuant to an Asset Purchase Agreement entered in February 2024.

We continue to advance the development of R289, our dual IRAK 1/4 inhibitor program, in an open-label, Phase 1b study to determine the tolerability and preliminary efficacy of the drug in patients with lower-risk MDS who are relapsed, refractory or resistant to prior therapies.

We have strategic development collaborations with MDACC to expand our evaluation of olutasidenib in AML and other hematologic cancers with IDH1 mutations, and with CONNECT to conduct a Phase 2 clinical trial to evaluate olutasidenib in combination with temozolomide in patients with HGG harboring an IDH1 mutation.

We have a RIPK1 inhibitor program in clinical development with our partner Lilly. We also have product candidates in clinical development with partners BerGenBio and Daiichi.

Reverse Stock Split

We filed with the Secretary of State of the State of Delaware a certificate of amendment to our Amended and Restated Certificate of Incorporation, to effect a 1-for-10 reverse stock split, effective June 27, 2024. As a result of the reverse stock split, every ten issued and outstanding shares of our common stock were automatically combined into one issued and outstanding share of common stock. Accordingly, an amount equal to the par value of the decreased shares resulting from the reverse stock split was reclassified from common stock to additional paid-in capital on the condensed balance sheet and statement of changes in stockholders' deficit. No fractional shares were issued in connection with the reverse stock split. Stockholders who otherwise would be entitled to receive fractional shares of common stock were entitled to receive the cash value equal to the fraction to which the stockholder would otherwise be entitled, multiplied by the closing price of the common stock as reported by Nasdaq on the last trading day prior to the effective date of the split. As a result of the reverse stock split, proportionate adjustments were made to the number of shares underlying (and as applicable, the exercise or conversion prices of) our outstanding equity awards and to the number of shares of common stock issuable under our equity incentive plans. The reverse stock split did not change the par value of our common stock, which remains $0.001, or the authorized number of shares of our common stock. All share amounts and per share amounts disclosed in this Quarterly Report on Form 10-Q have been adjusted to reflect the reverse stock split on a retroactive basis for all periods presented.

Business Updates

TAVALISSE IN ITP

For the nine months ended September 30, 2024, net product sales of TAVALISSE were $73.8 million, increased by $5.7 million or 8% compared to $68.1 million net product sales in the same period in 2023. The increase was primarily due to increased quantities sold, as well as increased price per bottle, partially offset by higher revenue reserves driven by increased government and private payor rebates.

REZLIDHIA in R/R AML with mIDH1

For the nine months ended September 30, 2024, net product sales of REZLIDHIA were $15.6 million, increased by $8.9 million or 133% compared to $6.7 million net product sales in the same period in 2023. The increase was primarily due to increased quantities sold primarily driven by increased number of patients under therapy, partially offset by higher revenue reserves primarily due to increased government rebates.

GAVRETO in metastatic RET fusion-positive NSCLC and advanced thyroid cancers

We began our commercialization and started recognizing revenue from product sales of GAVRETO in June 2024. For the nine months ended September 30, 2024, we recognized $9.0 million net product sales of GAVRETO. We believe GAVRETO is highly synergistic with our current product portfolio, and we expect to continue to leverage our existing commercial infrastructure to ensure current and newly prescribed GAVRETO patients have continued access to this important treatment option. We distribute and market GAVRETO for approved indications in RET fusion-positive NSCLC and advanced thyroid cancers. We acquired GAVRETO from Blueprint pursuant to an Asset Purchase Agreement entered into on February 22, 2024. Pursuant to the Asset Purchase Agreement, we purchased certain assets comprising the right to research, develop, manufacture and commercialize GAVRETO in the US from Blueprint. Under the terms of the agreement, we agreed to pay Blueprint a purchase price of $15.0 million, of which, $10.0 million was paid in July 2024 following our first commercial sale of GAVRETO at the end of June 2024, and an additional $5.0 million is payable on the first anniversary of the closing date of the agreement, subject to certain conditions. Blueprint is also eligible to receive up to $97.5 million in future commercial milestone payments and up to $5.0 million in future regulatory milestone payments, in addition to tiered royalties ranging from 10% to 30%.

Simultaneously and in conjunction with entering into the Asset Purchase Agreement, we also entered into certain supporting agreements, including a customary transition agreement, pursuant to which, during the transition period, Blueprint will transition regulatory and distribution responsibility for GAVRETO to us. We also agreed to purchase certain drug product inventories from Blueprint under a Material Transfer Agreement, and received such inventories amounting to approximately $6.5 million during the nine months ended September 30, 2024.

In October 2024, we issued a Dear Healthcare Provider Letter for GAVRETO related to a new safety signal identified in an ongoing Phase 3 clinical trial of pralsetinib in first-line treatment of RET fusion-positive, metastatic NSCLC patients, being conducted by Roche. The letter advises healthcare providers to apply certain measures to protect patient safety, including enhanced ongoing monitoring for signs and symptoms of infection as well as guidance for withholding treatment to patients in the presence of active infection.

R289, an Oral IRAK 1/4 Inhibitor for LR-MDS

We advanced the development of our dual IRAK 1/4 inhibitor program, following evaluation of single and multiple ascending doses of R289 in healthy subjects. The Phase 1b open-label, multicenter study evaluates the safety, tolerability and preliminary efficacy of R289 in patients with R/R lower-risk MDS. This Phase 1b study is expected to enroll approximately 40 patients (up to 30 participants in the dose escalation phase, and up to 10 participants in the dose expansion phase). The primary objective of the study is safety, with secondary and exploratory objectives to assess preliminary efficacy and characterize the pharmacokinetic and pharmacodynamic profile of R289. The safety and efficacy data from this Phase 1b study is intended to inform the recommended dose of R289 for further clinical evaluation in lower-risk MDS. Enrollment in the fifth dose level (500 mg / 250mg split dose) is underway. The initial data from the ongoing Phase 1b study will be presented at the 66th American Society of Hematology (ASH) Annual

Meeting and Exposition. Initial data indicate that R289 was generally well tolerated in a heavily pretreated LR-MDS patient population, the majority of whom were high transfusion burden at study entry. As of the data cutoff date (July 15, 2024), 14 of 19 patients were evaluable for efficacy; 4/11 patients receiving R289 doses ≥500 mg/daily achieved transfusion independence/hematologic improvement (HI-E) responses.

Olutasidenib in AML, Other Hematologic Cancers and HGG

In December 2023, we entered into a Strategic Collaboration Agreement with MDACC, a comprehensive cancer research, treatment, and prevention center. The collaboration will expand our evaluation of olutasidenib in AML and other hematologic cancers with IDH1 mutations. Under the Strategic Collaboration Agreement, we will jointly lead the clinical development efforts with MDACC to evaluate the potential of olutasidenib to treat newly diagnosed and R/R patients with AML, higher-risk MDS, and advanced myeloproliferative neoplasms, in combination with other agents. The collaboration will also support the evaluation of olutasidenib as monotherapy in patients with IDH1 mutated clonal cytopenia of undermined significance (CCUS) and lower-risk MDS, as well as maintenance therapy following hematopoietic stem cell transplant. Under the Strategic Collaboration Agreement, we will provide MDACC the study materials and $15.0 million in time-based milestone payments as compensation for services to be provided for the studies, over the five-year collaboration term, unless terminated earlier as provided for in the agreement. Through September 30, 2024, we provided $2.0 million funding to MDACC. In early August 2024, MDACC opened enrollment for a Phase 1b/2 triplet therapy trial of decitabine and venetoclax in combination with olutasidenib in patients with IDH1-mutated AML. In September 2024, we announced the first patient was enrolled. This is the first trial in our multi-year strategic development collaboration with MDACC. The Phase 1b part of the trial seeks to determine the safety and tolerability and recommended Phase 2 dose of decitabine and venetoclax in combination with olutasidenib. The primary objective of the Phase 2 part of the trial is to determine the complete remission rate in both newly diagnosed and R/R patients.

In January 2024, we announced our collaboration with Collaborative Network for Neuro-Oncology Clinical Trials (CONNECT), an international collaborative network of pediatric cancer centers, to conduct a Phase 2 clinical trial to evaluate olutasidenib in combination with temozolomide in patients with HGG harboring an IDH1 mutation (TarGet-D). Under the collaboration, CONNECT will include the olutasidenib treatment arm (TarGet-D) within CONNECT's TarGet study, a molecularly guided Phase 2 umbrella clinical trial for HGG. In our sponsored arm, adolescents and young adult patients (<39 years old) with newly-diagnosed IDH1-mutation positive HGG will receive maintenance therapy with olutasidenib in combination with temozolomide for the first year after radiotherapy, followed by olutasidenib monotherapy for the second year. Under the collaboration, we will provide CONNECT with a funding up to $3.0 million and study material over the four-year collaboration.

Collaboration and License Agreement with Kissei

In September 2024, we announced the expansion of our relationship with Kissei, granting exclusive rights to develop and commercialize olutasidenib in all human diseases in Japan, Korea and Taiwan, pursuant to a collaboration and license agreement. Under the terms of the agreement, we received a one-time, non-creditable upfront cash payment of $10.0 million from Kissei, with the potential for up to an additional $152.5 million in development, regulatory and commercial milestone payments, and will receive mid twenty to lower thirty percent, tiered, escalated net sales-based payments for the supply of olutasidenib, subject to certain customary reductions and offsets. Pursuant to the agreement, Kissei is responsible for companion diagnostic development in Japan, for which we will share fifty percent of the costs incurred by Kissei, up to $3.0 million, which are creditable against future milestones and transfer price payments owed to us. We remain responsible for the manufacture and supply of olutasidenib for all development and commercialization activities under the agreement. Pursuant to the concurrently executed supply agreement, we will supply Kissei with bulk drug product for use under the collaboration and license agreement.

We in-licensed olutasidenib from Forma with exclusive, worldwide rights for its development, manufacturing and commercialization. Under the agreement with Forma, Forma is entitled to a certain portion of sublicensing revenue, which include, but are not limited to, upfront payments, milestone payments and royalties, that we receive from a third party sublicensee. Following the collaboration and license agreement with Kissei, Forma is entitled to a portion of the sublicensing revenue from Kissei, including $2.3 million upon our receipt of the $10.0 million upfront cash payment which we expect to pay in the fourth quarter of 2024.

Global Strategic Partnership with Lilly

Lilly is continuing to advance ocadusertib (previously R552), an investigational, potent and selective RIPK1 inhibitor. Lilly has initiated the Phase 2a trial studying ocadusertib in adult patients with moderately to severely active rheumatoid arthritis. The Phase 2a enrollment of approximately 100 patients is advancing well, with preliminary analysis of the Phase 2a results anticipated in the first half of 2025. RIPK1 is implicated in a broad range of key inflammatory cellular processes and plays a key role in tumor necrosis factor signaling, especially in the induction of pro-inflammatory necroptosis. The program also includes RIPK1 compounds that cross the blood-brain barrier (CNS-penetrants) to address neurodegenerative diseases such as Alzheimer's disease and amyotrophic lateral sclerosis.

Under the Lilly Agreement, we are responsible for 20% of the development costs for ocadusertib in the US, Europe, and Japan, up to a specified cap, and Lilly is responsible for funding the remainder of all development activities for ocadusertib and other non-CNS disease development candidates. Under the Lilly Agreement, we have the right to opt-out of co-funding the ocadusertib development activities in the US, Europe and Japan at two different specified times and as a result receive lesser royalties from sales. In September 2023, we provided the first opt-out notice to Lilly and our funding commitment was capped at a specified amount through April 1, 2024, as provided for in the Lilly Agreement, as amended in September 2023. We provided $21.4 million funding to Lilly throughout the periods for our share for ocadusertib development costs incurred through April 1, 2024. Under the Lilly Agreement as amended, we have the right to opt-in to co-funding of ocadusertib development, upon us providing notice to Lilly within 30 days of certain events, as specified in the Lilly Agreement. If we decide to exercise our opt-in right, we will be required to continue to share in global development costs, and if we later exercise our second opt-out right (no later than April 1, 2025), our share in global development costs will be up to a specified cap through December 31, 2025, as provided for in the Lilly Agreement.

Patent Infringement Lawsuit

In June 2022, we received a notice letter regarding an Abbreviated New Drug Application (ANDA) submitted to the FDA by Annora Pharma Private Limited (Annora) requesting approval to market a generic version of TAVALISSE. In July 2022, we filed a lawsuit in the US District Court for the District of New Jersey against Annora and its subsidiaries for infringement of certain of our US patents. Litigation continues, and no trial date is currently set. For a more detailed discussion of this litigation matter, see Part II, Item 1, "Legal Proceedings" of this Quarterly Report on Form 10-Q.

Our Product Portfolio

The following table summarizes our portfolio:

	Indication	Target	Stage	Partner
Commercialized Products				
TAVALISSE® (fostamatinib)[1,2]	Adult Chronic ITP	SYK	Approved	
REZLIDHIA® (olutasidenib)[3]	R/R AML	mIDH1	Approved	
GAVRETO® (pralsetinib)[4]	RET+ NSCLC & Advanced Thyroid Cancer	RET	Approved	
Clinical Trials				
R289*	Lower-risk MDS	IRAK1/4	Phase 1b	
Partnered Programs				
Bemcentinib*	NSCLC	AXL	Phase 2	BerGenBio
Ocadusertib (previously R552)*	Rheumatoid Arthritis	RIPK1	Phase 2	Lilly
Milademetan*	Cancer	MDM2	Phase 1	Daiichi-Sankyo
Rxxx (CNS penetrant)	CNS Diseases	RIPK1	Pre-clinical	Lilly

Company-Sponsored Trials

[1] Please see the TAVALISSE Full Prescribing Information
[2] The product is also commercially available in Europe and the UK (TAVLESSE) as well as Canada, Israel and Japan (TAVALISSE) for the treatment of adult chronic immune thrombocytopenia (ITP).
[3] Please see the REZLIDHIA Full Prescribing Information, including Boxed WARNING
[4] Please see the GAVRETO Full Prescribing Information
* Investigational compound in this indication and has not been submitted for FDA review

Commercial Products

TAVALISSE/Fostamatinib in ITP

Chronic ITP affects an estimated 81,300 adult patients in the US. 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 (TPO) and splenectomy.

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 multicenter, 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 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. In October 2016, we

announced the results of the second FIT study, reporting that the response rate (16% in the treatment group, versus 4% in the placebo group) was consistent with the first study, although the difference was not statistically significant. 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, increased aspartate aminotransferase, 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. 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. In addition, a report describing the long-term safety and durable efficacy of TAVALISSE with up to five years of treatment was published in Therapeutic Advances in Hematology in 2021.

The FDA granted our request for orphan drug designation for fostamatinib for the treatment of ITP in August 2015. 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 US in May 2018.

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 currently available treatment options could be beneficial because 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 US that are approved by the FDA to increase platelet production through binding to TPO receptors on megakaryocyte precursors include PROMACTA® (Novartis International AG), Nplate® (Amgen, Inc.), DOPTELET® (Swedish Orphan Biovitrum AB) and ALVAIZ™ (Teva Pharmaceutical Industries Ltd.). In the longer term, we may eventually face competition from potential manufacturers of generic versions of our marketed products, including the proposed generic version of TAVALISSE that is the subject of an ANDA submitted to the FDA by Annora, which, if approved and allowed to enter the market, it could result in significant decreases in the revenue derived from sale of TAVALISSE and thereby materially harm our business and financial condition.

Commercial activities, including sales and marketing

Our marketing and sales efforts are focused on hematologists and hematologist-oncologists in the US who manage chronic adult ITP patients. We have a fully integrated commercial team consisting of sales, marketing, market access, and commercial operations functions. Our sales team promotes our products in the US using customary pharmaceutical company practices. Our products are 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 US, 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 US have appropriate access to our products, we have established a reimbursement and patient support program called Rigel OneCare ® (ROC). Through ROC, we provide co-pay assistance to qualified, commercially insured patients to help minimize out-of-pocket costs and provide free product 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.

We have entered into various license and commercial agreements to commercialize fostamatinib globally as discussed below, but we retain the global rights to fostamatinib outside of the respective territories under such license and commercial agreements.

Fostamatinib in EU and in the UK

We have a commercialization license agreement with Grifols for exclusive rights to commercialize fostamatinib for human diseases, and non-exclusive rights to develop, fostamatinib in their territory. Grifols territory includes EU, the UK, Turkey, the Middle East, North Africa and Russia (including Commonwealth of Independent States). In January 2020, the European Commission (EC) granted a centralized MA for fostamatinib (TAVLESSE) valid throughout the Europe and in the UK, after the departure of the UK from the EU, for the treatment of chronic ITP in adult patients who are refractory to other treatments. Grifols has launched TAVLESSE in the UK and certain countries in EU including Germany, France, Italy and Spain, and continues a phased rollout across the rest of EU.

Fostamatinib in Asia

We have an exclusive license and supply agreement with Kissei to develop and commercialize fostamatinib in all current and potential indications in Japan, China, Taiwan and 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. Japan has the third highest prevalence of chronic ITP in the world behind the US and Europe. Kissei was granted orphan drug designation from the Japanese Ministry of Health, Labor and Welfare for R788 (fostamatinib) in chronic ITP in February 2020. In December 2022, Japan's PMDA approved TAVALISSE for the treatment of chronic ITP, and in April 2023, Kissei launched TAVALISSE for chronic ITP in Japan.

Fostamatinib in Canada/Israel

We have exclusive commercial and license agreements with Medison to commercialize fostamatinib in all potential indications in Canada and Israel. 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. Medison launched TAVALISSE in Canada and Israel.

Fostamatinib in Latin America

We have a commercial license agreement with Knight to commercialize fostamatinib for approved indications in Latin America, consisting of Mexico, Central and South America, and the Caribbean. We are also responsible for the exclusive manufacture and supply of fostamatinib for all future development and commercialization activities under a commercial and supply agreement. In August 2023, Knight submitted the MAA for regulatory approval in Mexico, Colombia and Brazil for fostamatinib for the treatment of adult patients with ITP who had insufficient response to a previous treatment.

REZLIDHIA in R/R AML with mIDH1

mIDH1 alterations are seen in AML, MDS, glioma, chondrosarcoma, and intrahepatic cholangiocarcinoma. It is estimated that there are approximately 1,000 adult patients, a well-identified patient population, with mIDH1 R/R AML, part of an AML market estimated to have an incidence of approximately 20,000 cases in the US and an estimated 120,000 cases globally. Despite having approved treatment options for R/R AML patients who are mIDH1 positive, an unmet need remains.

Olutasidenib, an oral, small molecule drug designed to selectively bind to and inhibit mIDH1, is a treatment option with durable remissions, reduced QTc potential, and a stable pharmacokinetics profile that enables a consistent drug exposure over time. This targeted agent has the potential to provide therapeutic benefit by reducing 2-hydroxyglutarate levels and restoring normal cellular differentiation. IDH1 is a natural enzyme that is part of the normal metabolism of all cells. When mutated, IDH1 activity can promote blood malignancies and solid tumors. Olutasidenib was designated by the FDA as an orphan drug for the treatment of AML, which provides orphan drug market exclusivity from the time of marketing approval on December 1, 2022.

REZLIDHIA is designed to bind to and inhibit mIDH1 to reduce 2-hydroxyglutarate levels and restore normal cellular differentiation of myeloid cells. REZLIDHIA is a novel, non-intensive monotherapy treatment in the R/R AML setting demonstrating a CR+CRh rate of 35% in patients with over 90% of those responders in complete remission.

We in-licensed REZLIDHIA from Forma pursuant to a license and transition services agreement entered in July 2022, with exclusive, worldwide rights for development, manufacturing and commercialization of REZLIDHIA for any uses, including for the treatment of AML and other malignancies. In accordance with the terms of the license and transition services agreement, we paid an upfront fee of $2.0 million, with the potential to pay up to $67.5 million additional payments upon achievement of specified development and regulatory milestones and up to $165.5 million additional payments upon achievement of certain commercial milestones. In 2022, certain milestones were met which entitled Forma to receive a $17.5 million milestone payments. No new milestone was met in 2023 and during the nine months ended September 30, 2024. In addition, subject to the terms and conditions of the license and transition services agreement, Forma would be entitled to tiered royalty payments on net sales of licensed products at percentages ranging from low-teens to mid-thirties, as well as certain portions of our sublicensing revenue, subject to certain standard reductions and offsets.

In December 2022, the FDA approved REZLIDHIA capsules for the treatment of adult patients with R/R AML with IDH1 mutation as detected by an FDA-approved test, and we began the commercialization of REZLIDHIA and made it available to patients. The recommended dosage of REZLIDHIA is 150 mg taken orally twice daily until disease progression or unacceptable toxicity. The FDA approval was based on the NDA for olutasidenib for the treatment of m1DH1 R/R AML submitted by Forma, that had a PDUFA action date for the application of February 15, 2023. The NDA application was supported with a Phase 2 registrational trial for olutasidenib in mIDH1 R/R AML. Interim results from the Phase 2 registrational trial were reported at the American Society of Clinical Oncology (ASCO) annual meeting in June 2021. The interim results of this trial of 153 patients showed that olutasidenib demonstrated a favorable tolerability profile as a monotherapy in patients with R/R AML who have a susceptible mIDH1, and achieved a complete remission (CR) plus CR with partial hematologic recovery (CRh) rate of 33.3% (30% CR and 3% CRh), the primary efficacy endpoint. While a median duration of CR/CRh was not yet reached, a sensitivity analysis (with a hematopoietic stem cell transplant, as the end of a response) indicated the median duration of CR/CRh was 13.8 months**.** The overall response rate, comprised CR, CRh, Cri, partial response, and morphologic leukemia-free state (MLFS), was 46% and the median duration of overall response rate (ORR) was 11.7 months. The median overall survival was 10.5 months. For patients with CR/CRh, the median overall survival was not reached, but the estimated 18-month survival was 87%. The most frequently reported treatment emergent adverse events were nausea, constipation, increased white blood cell count, decreased red blood cell count, pyrexia, febrile neutropenia, and fatigue.

In November 2022, we announced the presentation of an updated interim analysis from the Phase 2 registrational trial of olutasidenib in patients with R/R AML demonstrated robust efficacy and safety results. The registrational cohort of the Phase 2 trial enrolled 153 patients with mIDH1 R/R AML who received olutasidenib monotherapy 150 mg twice daily. The efficacy evaluable population was 147 patients who received their first dose at least six months prior to the interim analysis cutoff date of June 18, 2021. The primary endpoint was a CR/CRh defined

as less than 5% blasts in the bone marrow, no evidence of disease, and partial recovery of peripheral blood counts (platelets >50,000/microliter and absolute neutrophil count >500/microliter). The results from the updated interim analysis of patients with mIDH1 R/R AML demonstrated a 35% CR+CRh rate with a median duration of 25.9 months. The ORR a secondary end point, was 48%, and was defined as the rate of CR, CRh, CR with incomplete blood count recovery (Cri), partial remission (which required recovery of neutrophil and platelet counts consistent with a CR), or MLFS. Olutasidenib was effective in a broad range of patients including those with prior high-intensity chemotherapy and/or post-venetoclax. The abstract concluded that the observed activity is clinically meaningful and represents a therapeutic advance in the treatment of this patient population. In this pivotal cohort, olutasidenib was well tolerated with an adverse event profile largely characteristic of symptoms or conditions experienced by patients undergoing treatment for AML or of the underlying disease itself.

In January 2023, we announced that REZLIDHIA has been added by the National Comprehensive Cancer Network (NCCN) to the latest NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for AML. REZLIDHIA is now included as a recommended targeted therapy for adult patients with R/R AML with IDH1 mutation.

In February 2023, we announced peer-reviewed publication data in *Blood Advances*, which summarize clinical results from the Phase 2 registrational trial of REZLIDHIA in patients with mIDH1 R/R AML. The published data demonstrate that REZLIDHIA induced durable remissions and transfusion independence with a well-characterized safety profile. The observed efficacy is clinically meaningful and represents a therapeutic advance in this poor prognosis patient population with limited treatment options. REZLIDHIA demonstrated both a high rate of response and an extended median duration of complete response of 28.1 months, which is more than a year longer than what is reported with the standard of care. In June 2023, we announced the second REZLIDHIA publication in *Blood Advances*, a review article examining the preclinical and clinical development, and the positioning of REZLIDHIA in the mIDH1 AML treatment landscape. The review concluded that the approval of REZLIDHIA is a critical addition to the mIDH1 AML treatment landscape. Further, the available data support the use of REZLIDHIA as monotherapy in R/R AML patients who have failed intensive chemotherapy or venetoclax plus hypomethylating agents combination therapy.

In June 2023, we announced presentation of data from an analysis from the Phase 2 study of REZLIDHIA in patients with mIDH1 AML who were previously treated with venetoclax. Data was featured in a poster presentation at the European Hematology Association (EHA) 2023 Hybrid Congress. The data support REZLIDHIA induced durable remissions in patients with mIDH1 AML in this poor-prognosis patient population who were R/R to venetoclax-based treatment.

In April 2024, we announced a peer-reviewed publication in *Leukemia & Lymphoma* on data from an analysis of the Phase 2 study evaluating REZLIDHIA in patients with mIDH1 AML who are R/R to prior venetoclax-based regimens. The findings from these analyses suggest that REZLIDHIA alone or in combination with azacitidine demonstrated potential efficacy in patients with AML following failure of venetoclax combination therapy.

In May 2024, we announced the presentation of the five-year results from the registrational Phase 2 trial of REZLIDHIA in R/R mIDH1 AML patients at the 2024 ASCO Annual Meeting and EHA 2024 Hybrid Congress. The data published reinforces REZLIDHIA's efficacy in heavily pretreated patients with mIDH1 AML, including those R/R to prior venetoclax. The safety profile was consistent with what was previously reported. Further, REZLIDHIA was generally well tolerated in elderly patients with R/R mIDH1 AML and induced durable remissions. Despite the challenges of treating elderly patients who had already failed prior AML treatment, the results suggest that elderly patients can benefit from therapy with REZLIDHIA. REZLIDHIA was also effective in achieving remission in patients with mIDH1 R/R AML and served as a bridging strategy towards potentially curative allogeneic transplantation in a substantial subset of these previously ineligible patients. Additionally, REZLIDHIA was well tolerated in a subset of patients with post-myeloproliferative neoplasms (MPN) mIDH1 AML, a patient population often associated with poor responses to available therapies.

Competitive landscape for REZLIDHIA

There is currently one other product approved in the US for patients with IDH1 mutation. The FDA granted approval to TIBSOVO® (ivosidenib), an oral targeted IDH1 mutation inhibitor, (i) in July 2018, for adult patients with R/R AML with a susceptible IDH1 mutation, (ii) in May 2019, for newly diagnosed AML with a susceptible IDH1

mutation who are at least 75 years old or who have comorbidities that preclude use of intensive induction chemotherapy, (iii) in August 2021, for adult patients with previously treated, locally advanced or metastatic cholangiocarcinoma with an IDH1 mutation as detected by an FDA-approved test, (iv) in May 2022, in combination with azacitidine (azacitidine for injection) for newly diagnosed AML with a susceptible IDH1 mutation, as detected by an FDA-approved test in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy, and (v) in October 2023, for adult patients with R/R MDS with a susceptible IDH1 mutation, as detected by an FDA-approved test. In addition, some clinicians may utilize non-targeted treatments for patients with mIDH1 R/R AML, including use of venetoclax combinations, hypomethylating agents, other chemotherapy regimens, or investigational agents that may be available to them.

Commercial activities, including sales and marketing

We believe REZLIDHIA is highly synergistic with our existing hematology-oncology focused commercial and medical affairs infrastructure. Our commercial effort focuses on growing awareness of REZLIDHIA within key institutions, and among targeted HCPs who manage patients with R/R AML with mIDH1. We retain the global rights, excluding Asian countries as discussed below, to develop and commercialize olutasidenib for all indications, and we are currently exploring other ex-US partnership opportunities.

Olutasidenib in Asia

In September 2024, we entered into a collaboration and license agreement with Kissei, pursuant to which Kissei was granted exclusive rights to develop and commercialize olutasidenib in all human diseases in Japan, Korea and Taiwan. Kissei will initially seek approval for REZLIDHIA in Japan for R/R mIDH1 AML and will be responsible for conducting clinical studies as required by the Japanese PMDA. We remain responsible for the manufacture and supply of olutasidenib for all development and commercialization activities and will supply Kissei with bulk drug product for use under the license and supply agreements.

Under the license and services agreement with Forma as discussed in “Note 5, In-licensing and Acquisition”, Forma is entitled to a certain portion of sublicensing revenue, which include, but are not limited to upfront payment, milestone payments and royalties, that we receive from a third party sublicensee. Following the license agreement with Kissei as discussed above, Forma is entitled to a portion of the sublicensing revenue we receive from Kissei.

GAVRETO in metastatic RET fusion-positive NSCLC and advanced thyroid cancers

RET is a receptor tyrosine kinase that activates multiple downstream pathways involved in cell proliferation and survival. RET can be activated by mutation or when a portion of the RET gene that encodes the kinase domain is joined to part of another gene creating a fusion gene that encodes an aberrantly activated RET fusion protein. RET alterations, such as fusions or mutations, drive the growth of multiple tumor types. It is estimated that over 230,000 adult patients in the US will be diagnosed with lung cancer in 2024. NSCLC is the most common type of lung cancer in the US accounting for 80-85% of all lung cancer diagnoses. RET activating fusions are key disease drivers in NSCLC. RET fusions are implicated in approximately 1-2% of patients with NSCLC.

We acquired the rights to research, develop, manufacture and commercialize GAVRETO from Blueprint, pursuant to an Asset Purchase Agreement entered in February 2024. GAVRETO is a once daily, small molecule, oral, kinase inhibitor of wild-type RET and oncogenic RET fusions. Currently, GAVRETO is one of only two approved RET inhibitors on the market for patients. GAVRETO is approved by the FDA for the treatment of adult patients with metastatic RET fusion-positive NSCLC as detected by an FDA-approved test. GAVRETO is also approved for the treatment of adult and pediatric patients 12 years of age and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate). This indication was approved by the FDA under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial. Discussions with the FDA regarding confirmatory requirements are ongoing.

On June 24, 2024, we announced the completion of the transfer to us of the NDA for GAVRETO, and GAVRETO is commercially available from us in the US by prescription beginning June 27, 2024. GAVRETO was co-marketed by Blueprint and Genentech, a member of Roche Group (Roche), to patients in the US since September 2020 pursuant to a collaboration agreement between Blueprint and Roche, which was terminated effective in February 2024.

The patent portfolio covering pralsetinib contains patents and patent applications directed to compositions of matter for pralsetinib, including solid forms, formulations, and methods of use and manufacture. Pralsetinib is covered as a composition of matter in a US issued patent that has an expiration date in November 2036 and subject to potential extensions. Patents that have been issued or are expected to be issued covering pralsetinib will have statutory expiration dates between 2036 and 2041. The FDA granted GAVRETO new chemical entity exclusivity until September 2025 and orphan drug exclusivity until September 2027 with respect to the approval for treatment of adult patients with metastatic RET fusion-positive NSCLC as detected by an FDA-approved test. The FDA also granted GAVRETO two orphan drug exclusivities until December 2027 with respect to FDA approval for the treatment of adult and pediatric patients 12 years of age and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate), and for the treatment of adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid carcinoma who require systemic therapy.

Competitive landscape for GAVRETO

GAVRETO faces competition for RET fusion-positive NSCLC and advanced thyroid cancers from Lilly's selpercatinib. In addition, other commercially available therapies used to treat RET fusion-positive NSCLC include cabozantanib and platinum-based chemotherapy regimens with or without pembrolizumab, atezolizumab, nivolumab/ipilumumab, cemiplimab or tremelimumab-durvalumab. Pralsetinib may also face competition from other drug candidates in development for RET-altered cancers, as well as multi-kinase inhibitors with RET activity being evaluated in clinical trials.

Commercial activities, including sales and marketing

We began our commercialization and started recognizing revenue from product sales of GAVRETO in June 2024. We believe GAVRETO is highly synergistic with our current product portfolio, and we expect to continue to leverage our existing commercial infrastructure to ensure current and newly prescribed GAVRETO patients have continued access to this important treatment option. We distribute and market GAVRETO for approved indications in RET fusion-positive NSCLC and advanced thyroid cancers.

Clinical Stage Programs

R289, an Oral IRAK 1/4 Inhibitor for Hematology-Oncology, Autoimmune, and Inflammatory Diseases

During the second quarter of 2018, we selected R835, a proprietary molecule from our dual IRAK 1/4 inhibitor program, for human clinical trials. This investigational candidate is 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 receptor (IL-1R) family 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. R835 prevents cytokine release in response to TLR and IL-1R activation in vitro, and 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 than inhibition of either one individually.

In October 2019, we announced results from a Phase 1 randomized, placebo-controlled, double-blind clinical study evaluating the safety, tolerability, pharmacokinetics (PK) and pharmacodynamics of R835 in 91 healthy adult subjects. The Phase 1 study showed that R835 had a favorable safety, tolerability and PK profile and established proof-of-mechanism by demonstrating the inhibition of inflammatory cytokine production in response to a lipopolysaccharide (LPS) challenge.

We advanced the development of our IRAK 1/4 inhibitor program, following evaluation of single and multiple ascending doses of R289, a new pro-drug formulation of R835 in healthy subjects. In January 2022, we received clearance from the FDA to initiate a Phase 1b open-label, multicenter study to evaluate the safety, tolerability and preliminary efficacy of R289 in patients with R/R lower-risk MDS. In December 2022, we announced the dosing of the first patient. This Phase 1b study is expected to enroll approximately 40 patients (up to 30 participants in the dose escalation phase, and up to 10 participants in the dose expansion phase). The primary objective of the study is safety, with secondary and exploratory objectives to assess preliminary efficacy and characterize the pharmacokinetic and pharmacodynamic profile of R289. The safety and efficacy data from this Phase 1b study is intended to inform the recommended dose of R289 for further clinical evaluation in lower-risk MDS. Enrollment in the fifth dose level (500 mg / 250mg split dose) is underway. The initial data from the ongoing Phase 1b study will be presented at the 66th ASH Annual Meeting and Exposition. Initial data indicate that R289 was generally well tolerated in a heavily pretreated LR-MDS patient population, the majority of whom were high transfusion burden at study entry. As of the data cutoff date (July 15, 2024), 14 of 19 patients were evaluable for efficacy; 4/11 patients receiving R289 doses ≥500 mg/daily achieved transfusion independence/hematologic improvement (HI-E) responses.

Olutasidenib for mIDH1 AML

We have a strategic collaboration agreement with MDACC to expand our evaluation of olutasidenib in AML and other hematologic cancers with IDH1 mutations. Under such collaboration agreement, we will jointly lead the clinical development efforts with MDACC to evaluate the potential of olutasidenib to treat newly diagnosed and R/R patients with AML, higher-risk MDS, and advanced myeloproliferative neoplasms, in combination with other agents. The collaboration will also support the evaluation of olutasidenib as monotherapy in patients with IDH1 mutated clonal cytopenia of undermined significance and lower-risk MDS, as well as maintenance therapy following hematopoietic stem cell transplant. In early August 2024, MDACC opened enrollment for a Phase 1b/2 triplet therapy trial of decitabine and venetoclax in combination with olutasidenib in patients with IDH1-mutated AML. In September 2024, we announced the first patient was enrolled. This is the first trial in our multi-year strategic development collaboration with MDACC. The Phase 1b part of the trial seeks to determine the safety and tolerability and recommended Phase 2 dose of decitabine and venetoclax in combination with olutasidenib. The primary objective of the Phase 2 part of the trial is to determine the complete remission rate in both newly diagnosed and R/R patients.

Partnered Clinical Programs

Ocadusertib – Lilly

Lilly is continuing to advance ocadusertib (previously R552) and has initiated the Phase 2a trial studying ocadusertib in adult patients with moderately to severely active rheumatoid arthritis. The Phase 2a enrollment of approximately 100 patients is advancing well, with preliminary analysis of the Phase 2a results anticipated in the first half of 2025. RIPK1 is implicated in a broad range of key inflammatory cellular processes and plays a key role in tumor necrosis factor signaling, especially in the induction of pro-inflammatory necroptosis. The program also includes RIPK1 compounds that cross the blood-brain barrier (CNS-penetrants) to address neurodegenerative diseases such as Alzheimer's disease and amyotrophic lateral sclerosis.

Bemcentinib – BerGenBio

We have an exclusive, worldwide research, development and commercialization agreement with BerGenBio for our investigational AXL receptor tyrosine kinase inhibitor, R428 (now referred to as bemcentinib (BGB324)). In February 2023, BerGenBio announced positive data from the Phase 2 trial of bemcentinib in combination with pembrolizumab in patients with second-line NSCLC. The treatment with bemcentinib in combination with pembrolizumab demonstrated long survival benefit and sustained disease control, particularly in patients with AXL TPS > 5, substantiating the relevance of AXL as a target and bemcentinib's selective inhibition capabilities in NSCLC. Also in March 2023, BerGenBio announced its first patient dosed in a Phase 1b/2a trial evaluating bemcentinib in first-line NSCLC patients harboring STK11 mutations. In March 2024, BerGenBio announced initiation of the Phase 2a portion of the study following a positive decision by the Data and Safety Monitoring Board (DSMB) following review of the Phase 1b safety data. In July 2024, BerGenBio announced that the DSMB confirmed acceptable safety at the highest dose tested in Phase 1b and recommended that under the study protocol, no additional patients will be required for Phase

1b. In October 2024, BerGenBio announced the preliminary safety data from dose escalation Phase 1b in first-line NSCLC patients.

Milademetan – Daiichi

DS-3032 is an investigational oral selective inhibitor of the 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 trial of DS-3032 suggests that DS-3032 may be a promising treatment for hematological malignancies including R/R AML and high-risk MDS. In September 2020, worldwide rights to DS-3032 (milademetan) were out-licensed from Daiichi to Rain Oncology Inc. (Rain). In January 2024, Pathos Al, Inc. (Pathos) completed the acquisition of Rain. Pathos indicated that it has continued interest in further developing milademetan for cancer patients using its propriety PathOS Platform.

Research, Preclinical and Clinical Development Programs

We have retained selected experts in drug discovery and preclinical development to leverage our existing proprietary collection of inhibitors, small-molecule compound libraries and large database of associated phenotypic and biochemical assay results of therapeutic interest. We maintain leading expertise on specific areas of operation such as inhibition of SYK, IRAK 1/4, RIPK1 and mIDH1 kinases to assist clinical development and commercial affairs, as well as to expand and explore additional opportunities for such inhibitors in the clinical space. Our preclinical operations involve collaborations with clinical research organizations, leading investigators from universities and research organizations around the world, and strategic collaborations with other pharmaceutical companies.

We have experts in drug development to design and implement clinical trials and to analyze the data derived from these trials. The clinical development group possesses expertise in project management and regulatory affairs. We work with external clinical research organizations with expertise in managing clinical trials, drug formulation, and the manufacture of clinical trial supplies to support our drug development efforts.

We also have strategic development collaborations with MDACC and CONNECT to conduct evaluation of olutasidenib in AML, other hematologic cancers and glioma.

Commercialization and Sponsored Research and License Agreements

See “Note 4 – Sponsored Research, License Agreements and Government Contracts” and “Note 5 – In-licensing and Acquisition” to our “Notes to Condensed Financial Statements” contained in Part I, Item 1 of this Quarterly Report on Form 10-Q for related discussions.

Results of Operations

Revenues

	Three Months Ended September 30,		Aggregate	Nine Months Ended September 30,		Aggregate
	2024	2023	Change	2024	2023	Change
			(in thousands)			
Product sales, net	$ 38,927	$ 27,129	$ 11,798	$ 98,380	$ 74,755	$ 23,625
Contract revenues from collaborations	16,380	1,005	15,375	23,302	5,335	17,967
Government contracts	—	—	—	—	1,000	(1,000)
Total revenues	$ 55,307	$ 28,134	$ 27,173	$ 121,682	$ 81,090	$ 40,592

The following table summarizes the percentages of revenues from each of our customers who individually accounted for 10% or more of the total net product sales and revenues from collaborations:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
McKesson Corporation	43%	49%	44%	46%
Cencora Inc. (formerly ASD Healthcare)	19%	18%	20%	20%
Cardinal Health, Inc.	*	28%	15%	27%
Kissei	23%	*	14%	*

* Denotes less than 10%

Revenue from product sales is related to our sale of our products in the US, net of chargebacks, discounts and fees, government and other rebates and returns. Typically, our first quarter net sales are impacted by the first quarter reimbursement issues such as the resetting of co-pays and the Medicare donut hole.

TAVALISSE net product sales for the three and nine months ended September 30, 2024 were $26.3 million and $73.8 million, respectively, increased by 8% for each period, compared to $24.5 million and $68.1 million net product sales for the three and nine months ended September 30, 2023, respectively. The increase was primarily due to increased quantities sold, as well as increased price per bottle, partially offset by higher revenue reserves driven by increased government and private payor rebates. REZLIDHIA net product sales in the three and nine months ended September 30, 2024 were $5.5 million and $15.6 million, respectively, increased by 107% and 133% compared to $2.7 million and $6.7 million net product sales for the three and nine months ended September 30, 2023, respectively. The increase was primarily due to increased quantities sold primarily driven by increased number of patients under therapy, partially offset by the higher revenue reserves primarily due to increased government rebates. Following the commercialization of GAVRETO in June 2024, we started recognizing revenue from shipments to our distributors. For the three and nine months ended September 30, 2024, we recognized $7.1 million and $9.0 million, respectively, of GAVRETO net product sales.

Contract revenues from collaborations in the three and nine months ended September 30, 2024 consisted primarily of revenue from Kissei of $13.0 million and $17.5 million, respectively, $10.0 million of which was the upfront fee we received from sublicensing olutasidenib, and the remainder was related to the delivery of drug supplies. In addition, we recognized revenue from Grifols of $3.3 million and $5.5 million in the three and nine months ended September 30, 2024, respectively, related to earned royalty and delivery of drug supplies. Contract revenues from collaborations in the three and nine months ended September 30, 2023 consisted primarily of revenue from Grifols of $0.8 million and $5.1 million, respectively, related to earned royalty and delivery of drug supplies.

No government contract revenue was recognized during the three and nine months ended September 30, 2024, and three months ended September 30, 2023. Government contract revenue in the nine months ended September 30, 2023 was related to the income we recognized upon achievement of certain milestones from the award granted to us by the DOD.

We expect that our future revenues to include product sales of our existing commercial products and product sales from new commercial products we may have in the future. Our net product sales may be impacted by the demand from our customers, changes to government and private payor rebate programs, chargeback and discount programs, co-payment assistance programs, and any other rebate and discount programs we may enter in the future. In addition, our future revenues may include payments from our existing and new collaboration partners and government grants. As of September 30, 2024, we had $1.4 million of deferred revenue relating to our collaboration agreement with Kissei which we will recognize as revenue upon satisfaction of our remaining performance obligations.

Cost of Product Sales

	Three Months Ended September 30,		Aggregate	Nine Months Ended September 30,		Aggregate
	2024	2023	Change	2024	2023	Change
			(in thousands)			
Cost of product sales	$ 8,026	$ 1,268	$ 6,758	$ 12,858	$ 3,320	$ 9,538

The cost of product sales includes the cost of inventories sold to our customers and to our collaborative partners. Inventories sold for the periods presented include inventory quantities acquired or produced prior to the FDA approval of the product, and do not reflect the full cost of the inventories sold, since such costs incurred prior to FDA approval were previously expensed and charged to research and development expense. In particular, we still utilize active pharmaceutical ingredients with zero cost for our TAVALISSE inventories, which we expect to make use of for the next 1 to 2 years. As such, we recognize lower cost of product sales in the periods where we sell inventory quantities acquired or produced prior to the FDA approval of the product. As we acquire or produce more FDA approved inventory quantities in the future, our inventory cost in the balance sheet and cost of product sales will reflect the full cost of acquiring or producing such products. Cost of product sales also includes amortization of intangible assets acquired from in-licensing or acquisition of commercialized products, as well as sublicensing revenue fees and royalty expense. Cost of product sales may also include reserves for potential excess, dated or obsolete inventories, estimated based upon assumptions about future demand and market conditions as well as product shelf lives.

The increase in cost of product sales in the three and nine months ended September 30, 2024 compared to the same periods in 2023 was primarily due to increased royalty expense and sublicensing revenue fee of $3.4 million and $4.5 million, respectively, and increased amortization of intangible assets of $0.3 million and $0.7 million, respectively. Further, the increase in cost of product sales was also partly due to increased product sales, and increased delivery of drug supplies pursuant to our supply agreements with our collaborative partners.

Research and Development Expense

	Three Months Ended September 30,		Aggregate	Nine Months Ended September 30,		Aggregate
	2024	2023	Change	2024	2023	Change
			(in thousands)			
Research and development expense	$ 6,182	$ 6,475	$ (293)	$ 17,748	$ 21,336	$ (3,588)
Stock-based compensation expense included in research and development expense	$ 284	$ 347	$ (63)	$ 1,239	$ 1,746	$ (507)

Research and development expense in the three months ended September 30, 2024 decreased compared to the same period in 2023. The decrease in research and development expense primarily due to timing of progress of trial activities of our IRAK 1/4 inhibitor program of $1.7 million and in other various research and development costs of $0.2 million, were partially offset by the increase in our research and development expense related to our ongoing clinical development programs for olutasidenib of approximately $1.6 million.

The decrease in research and development expense in the nine months ended September 30, 2024 compared to the same period in 2023 was partly due to decreased clinical trial related expenses of $2.8 million due to the progress of trial activities of our IRAK 1/4 inhibitor program, as well as $1.8 million due to timing of trial activities of our completed Phase 3 clinical trials of fostamatinib in patients with COVID-19 and wAIHA. Other research and development expense including allocated facilities and laboratory costs also decreased by $1.0 million. These decreases

were partially offset by the increase in our research and development activities of $2.0 million related to our ongoing clinical development programs for olutasidenib.

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 to continue to incur significant research and development expense as we continue our activities in our clinical studies including IRAK 1/4 inhibitor program; our collaborative partnerships with MDACC and CONNECT to evaluate olutasidenib in AML, other hematologic cancers and glioma; and any other clinical programs we may pursue in the future.

We do not track fully burdened research and development costs separately for each of our drug candidates. We review our research and development expense by focusing on three categories: research, development, and other. Our research team is focused on identifying and evaluating product candidates in our focused range of therapeutic indications that can be developed into small molecule therapeutics in our own proprietary programs or with potential collaborative partners. “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 our regulatory filings, 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 expense 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.

Preclinical testing and clinical development are long, expensive and uncertain processes, and we cannot reliably predict the timing of such clinical trial activities. 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*
	2024	2023	2024	2023	to September 30, 2024
Categories:					
Research	$ 37	$ 375	$ 898	1,332	$ 269,954
Development	5,757	5,616	15,224	17,379	577,699
Other	388	484	1,626	2,625	278,876
	$ 6,182	$ 6,475	$ 17,748	$ 21,336	$ 1,126,529

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

"Other" expenses in the three months ended September 30, 2024 and 2023 consisted of allocated facilities costs of $0.1 million for each of the periods, and allocated stock-based compensation expense of $0.3 million and $0.4 million, respectively. For the nine months ended September 30, 2024 and 2023, allocated facilities costs was $0.4 million and $0.9 million, respectively, and allocated stock-based compensation expense was $1.2 million and $1.7 million, respectively.

Selling, General and Administrative Expense

	Three Months Ended September 30,		Aggregate	Nine Months Ended September 30,		Aggregate
	2024	2023	Change	2024	2023	Change
			(in thousands)			
Selling, general and administrative expense	$ 27,043	$ 24,856	$ 2,187	$ 83,539	$ 78,891	$ 4,648
Stock-based compensation expense included in selling, general and administrative expense	$ 2,360	$ 1,596	$ 764	$ 9,067	$ 5,127	$ 3,940

The increase in selling, general and administrative expense in the three months ended September 30, 2024 compared to the same period in 2023 was primarily due to increases in commercial related expenses of $1.9 million and in personnel-related costs and stock-based compensation expense of $1.5 million, partially offset by the decrease in other various sales, general and administrative costs of $1.2 million.

The increase in selling, general and administrative expense in the nine months ended September 30, 2024 compared to the same period in 2023 was primarily due to increases of $5.9 million in personnel-related costs and stock-based compensation expense, and in commercial related expenses of $1.7 million, partially offset by the decrease in other various sales, general and administrative costs primarily due to lower facilities cost of $3.0 million.

We expect to incur significant selling, general and administrative expenses, as we expect our commercial related expenses to increase as we continue to expand our commercial activities for TAVALISSE, REZLIDHIA, and GAVRETO. We continue to deploy resources to enable our field-based employees to engage with healthcare providers. These engagements have enabled our field team to cover existing prescribers, as well as develop relationships with new prescribers to identify appropriate patients for our products.

Interest Income and Interest Expense

	Three Months Ended September 30,		Aggregate	September 30,		Aggregate
	2024	2023	Change	2024	2023	Change
			(in thousands)			
Interest income	$ 425	$ 672	$ (247)	$ 1,570	$ 1,594	$ (24)
Interest expense	$ (2,060)	$ (1,899)	$ (161)	$ (5,963)	$ (4,965)	$ (998)

Interest income is related to our interest-bearing cash and investment balances. The decrease in interest income in the three and nine months ended September 30, 2024 compared to the same periods in 2023 was primarily driven by lower investment balances throughout the respective periods, partially offset by higher interest rates.

Interest expense was comprised primarily of interest on the outstanding term loan with MidCap. Increased interest expense in the three and nine months ended September 30, 2024 compared to the same periods in 2023 was primarily due to higher interest on our term loan with Midcap. Also contributing to higher interest expense for the nine months ended September 30, 2024 compared to the same period in 2023 was the higher outstanding principal balance of the term loan throughout the respective periods as the Tranche 5 ($20.0 million) term loan was funded in March 2023.

Critical Accounting Policies and 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 US 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. 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.

Our critical accounting estimates and significant accounting policies are described in “Note 1 – Description of Business and Summary of Significant Accounting Policies” to our “Notes to Financial Statements” contained in Part II, Item 8, “Financial Statements and Supplementary Data” of our Annual Report on Form 10-K for the year ended December 31, 2023. There have been no material changes to these accounting policies except for the accounting consideration related to the Asset Purchase Agreement with Blueprint as discussed in “Note 5 – In-licensing and Acquisition” to our “Notes to Condensed Financial Statements” contained in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Recent Accounting Pronouncements

See related discussions of recently issued accounting standards in “Note 1 – Organization and Summary of Significant Accounting Policies” to our “Notes to Condensed Financial Statements” contained in Part I, Item 1 of this Quarterly Report on Form 10-Q. 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, 2024 and December 31, 2023, we had approximately $61.1 million and $56.9 million, respectively, in cash, cash equivalents and short-term investments. We continue to maintain investment portfolios primarily in money market funds, US treasury bills, government-sponsored enterprise securities, 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,	
	2024	2023
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ 16,968	$ 497
Investing activities	15,044	2,577
Financing activities	(13,106)	17,881
Net increase in cash and cash equivalents	$ 18,906	$ 20,955

Net cash provided by operating activities for the nine months ended September 30, 2024 was primarily due the proceeds from sales of our products, and cash received from our collaboration partners including the $10.0 million upfront payment from Kissei pursuant to the collaboration and license agreement, partially offset by the payments of operating expenses. Net cash provided by operating activities for the nine months ended September 30, 2023 was primarily due to the proceeds from sales of our products, cash received from our collaboration partners including the $20.0 million regulatory milestone payment from Kissei received in January 2023, as well as cash received from government grants, partially offset by payments of operating expenses.

Net cash provided by investing activities for the nine months ended September 30, 2024 comprised primarily of net maturities of short-term investments of $15.4 million, partially offset by payments for acquisition of intangible assets of $0.4 million. Net cash provided by investing activities for the nine months ended September 30, 2023 comprised net maturities of short-term investments of $17.4 million and proceeds from sale of property and equipment of $0.1 million, partially offset by the payment of milestone obligations to Forma recorded as intangible assets of $15.0 million.

Net cash used in financing activities for the nine months ended September 30, 2024 comprised payment of the closing purchase price to Blueprint of $10.0 million and cost share payments to a collaboration partner of $3.6 million, partially offset by the net proceeds from issuance of common stock upon exercise of stock options and participation in the Purchase Plan of $0.5 million. Net cash provided by financing activities for the nine months ended September 30, 2023 comprised net cash proceeds from term loan financing of $20.0 million (Tranche 5) and proceeds from exercise of stock options and participation in the Purchase Plan of $0.6 million, partially offset by our cost share payments to collaboration partner of $2.6 million.

We believe that our existing capital resources will be sufficient to support our current and projected funding requirements, including the continued commercialization of our products, through at least the next 12 months from this 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

We finance our operations primarily through sales of our products, and contract payments under our collaboration agreements, as well as through equity securities and debt financing.

Under our existing collaboration agreements that we entered 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. As of September 30, 2024, total future contingent payments to us under our existing agreements could exceed $1.4 billion if all potential product candidates achieved all of the payment triggering events under all of our current agreements. 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. See further discussion in "Note 4 – Sponsored Research, License Agreements and Government Contracts" to our "Notes to Condensed Financial Statements" contained in Part I, Item 1 of this Quarterly Report on Form 10-Q.

We have an Open Market Sale Agreement with Jefferies LLC (Jefferies), as a sole agent, entered on August 4, 2020, and amended and restated on August 2, 2024. Pursuant to such Open Market Sale Agreement, 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. As of September 30, 2024, we have not sold any shares of common stock under such Open Market Sale Agreement. We had a shelf registration statement (the Prior Registration Statement) filed with the SEC that expired on August 3, 2024. The Prior Registration Statement included a base prospectus registering the offering, issuance, and sale by us of up to $250.0 million in the aggregate of the securities identified from time to time in one or more offerings, including the $100.0 million of shares of our common stock that may be offered, issued and sold under the Open Market Sale Agreement. On August 2, 2024, we filed a new shelf registration statement (the New Registration Statement) with the SEC to replace the Prior Registration Statement. The New Registration Statement was declared effective on August 9, 2024 by the SEC. The New Registration Statement includes a base prospectus to register the offering, issuance and sale by us of up to $250.0 million in the aggregate of securities identified from time to time in one or more offerings, including up to $100.0 million of shares of our common stock that may be offered, issued and sold under the Open Market Sale Agreement.

We have a Credit Agreement with MidCap that provides for $60.0 million term loan credit facility, which was fully funded as of September 30, 2024.

Our operations will require significant additional funding in the foreseeable future. Unless and until we can generate sufficient cash from our operating activities, we may choose to raise additional funds through public and/or private offerings of equity securities, debt financings, or from other sources. However, certain external factors such as global pandemics, the global tensions arising from the Russia-Ukraine war and Hamas-Israel war, political and economic legislations, and other factors may continue to rapidly evolve which could significantly disrupt the global financial markets. Our ability to raise additional funds may be adversely impacted by potential worsening of global economic conditions and volatility in the credit and financial markets in the US and worldwide. We could experience an inability to access additional funds, which could in the future negatively affect our capacity for certain corporate development transactions or our ability to make important, opportunistic investments. To the extent that we raise additional funds through the sale of equity, our shareholders' ownership interest may experience substantial dilution. Our current credit facility with MidCap and any debt financing that we can 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 our products, or any other future product candidates, if any such candidate receives regulatory approval for commercial sale;
- our ability to generate expected revenue from our commercialization efforts;

- 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 secure and maintain our patent protection and regulatory rights;
- 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 US;
- 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, including regulatory rights such as regulatory data exclusivities; 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 (CROs) 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 including our strategic development collaborations with MDACC and CONNECT, as well as with third parties relative to our commercialization of our products. 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 trials, and various activities related to commercialization. We expect that 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 commercialization of our products. 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 4 – Sponsored Research, License Agreements and Government Contracts” of our “Notes to Condensed Financial Statements” contained in Part I, Item 1 of this Quarterly Report on Form 10-Q, pursuant to the amended Lilly Agreement, and us providing the first opt-out notice to Lilly on September 29, 2023, we were responsible for funding the development costs for ocadusertib (previously R552) in the US, Europe, and Japan, through April 1, 2024, capped at a specified amount. Lilly billed us $21.4 million of the funding development costs

incurred through April 1, 2024 and the amount was fully paid as of September 30, 2024. Although currently we are no longer obligated to pay Lilly for our share in the ocadusertib development cost incurred subsequent to April 1, 2024, under the Lilly Agreement, we have the right to opt-in to co-funding the ocadusertib development, upon us providing notice to Lilly within 30 days of certain events, as specified in the Lilly Agreement. If we decide to exercise our opt-in right, we will be required to continue to share in global development costs, and if we later exercise our second opt-out right (no later than April 1, 2025), our share in global development costs will be up to a specified cap through December 31, 2025, as provided for in the Lilly Agreement.

As discussed in detail in “Note 5 – In-licensing and Acquisition” of our “Notes to Condensed Financial Statements” contained in Part I, Item 1 of this Quarterly Report on Form 10-Q, pursuant to an Asset Purchase Agreement with Blueprint entered in February 2024, we agreed to pay Blueprint a purchase price of $15.0 million, of which, $10.0 million was paid in July 2024, and an additional $5.0 million is payable on the first anniversary of the closing date of the agreement, subject to certain conditions. Blueprint is also eligible to receive up to $97.5 million in future commercial milestone payments, up to $5.0 million in future regulatory milestone payments, and tiered royalty payments ranging from 10% to 30%.

Additionally, as discussed in detail in “Note 5 – In-licensing and Acquisition” of our “Notes to Condensed Financial Statements” contained in Part I, Item 1 of this Quarterly Report on Form 10-Q, pursuant to our license and transition services agreement, Forma is entitled to potential development and regulatory milestone payments of up to $67.5 million, commercial milestone payments of up to $165.5 million, and tiered royalty payments on net sales as well as certain portion of sublicensing revenue. Certain milestones were met in 2022 which entitled Forma to receive $17.5 million milestone payments that was paid in the fourth quarter of 2022 and first quarter of 2023. No additional milestone was met through September 30, 2024. As discussed in “Note 4 – Sponsored Research, License Agreements and Government Contracts” of our “Notes to Condensed Financial Statements” contained in Part I, Item 1 of this Quarterly Report on Form 10-Q, Forma is entitled to a portion of the sublicensing revenue we receive from Kissei related to our collaboration and license agreement of olutasidenib. With the receipt of the upfront payment of $10.0 million from Kissei in September 2024, Forma is entitled to $2.3 million sublicense revenue fee, which we expect to pay in the fourth quarter of 2024.

As of September 30, 2024, we have a contractual commitment related to our leased facilities of $0.5 million and the amount is payable within 12 months. See “Note 11 – Leases” to our “Notes to Condensed Financial Statements” contained in Part I, Item 1 of this Quarterly Report on Form 10-Q for further discussions of our leases.

As discussed above, we have a contractual commitment with respect to our credit facility with MidCap, and as of September 30, 2024, the outstanding principal amount of the loan was $60.0 million. As discussed in detail in “Note 10 – Debt” to our “Notes to Condensed Financial Statements” contained in Part I, Item 1 of this Quarterly Report on Form 10-Q, the term loans mature on September 1, 2027, and the interest-only period is through October 1, 2025. The term loans bear interest equal to the sum of one-month SOFR plus an adjustment of 0.11448%, subject to a 4.00% applicable floor, plus applicable margin of 6.50%. A final payment fee of 4.25% of principal is due at maturity date. As of September 30, 2024, no principal payments are due within 12 months. As of September 30, 2024, future interest calculated using the base interest rate as per the amended Credit Agreement, and the final fee payments associated with the credit facility amounted to $16.0 million, of which, approximately $6.6 million is payable within 12 months.

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. We do not have other material contractual commitments with respect to matters discussed above.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities related to our investments and borrowings. There were no material changes to our quantitative and qualitative disclosures about market risks during the nine months ended September 30, 2024 as disclosed in "Item 7A. Quantitative and Qualitative Disclosures About Market Risks" of our Annual Report on Form 10-K for the year ended December 31, 2023.

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, 2024 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

From time to time, we may be a party or subject to legal proceedings and claims, either asserted or unasserted, which arise in the ordinary course of business. Some of these proceedings that we may be involved in the future, are claims that are subject to substantial uncertainties and unascertainable damages or other remedies.

Our threshold for disclosing material environmental legal proceedings involving a government authority where potential monetary sanctions are involved is $1.0 million.

In June 2022, we received a notice letter regarding an ANDA submitted to the FDA by Annora Pharma Private Limited (Annora), requesting approval to market a generic version of TAVALISSE. The notice letter included a Paragraph IV certification with respect to our US Patent Nos. 7,449,458; 8,263,122; 8,652,492; 8,771,648 and 8,951,504, which are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (referred to as the "Orange Book"). The notice letter asserts that these patents will not be infringed by Annora's proposed product, are invalid and/or are unenforceable. Annora's notice letter does not provide a Paragraph IV certification against our other patents listed in the Orange Book. On July 25, 2022, we filed a lawsuit in the US District Court for the District of New Jersey against Annora and its affiliates, Hetero Labs Ltd., and Hetero USA, Inc., for infringement of our US patents identified in Annora's Paragraph IV certification. On September 21, 2022, Annora and its affiliates answered and counterclaimed for declaratory judgment of non-infringement and invalidity of the '458, '122, '492, '648, and '504 patents. We served an answer to Annora's counterclaims in October 2022. Annora served invalidity and non-infringement contentions in December 2022. We served an answer to Annora's invalidity and non-infringement contentions in March 2023. Litigation continues, and no trial date is currently set. We intend to vigorously enforce and defend our intellectual property related to TAVALISSE.

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 for the year ended December 31, 2023 filed with the SEC on March 5, 2024, if any.

Risk Factor Summary

- Our prospects are highly dependent on our existing commercial products, TAVALISSE (fostamatinib disodium hexahydrate), REZLIDHIA (olutasidenib), and GAVRETO (pralsetinib). To the extent that the commercial success of our products in the US and respective territories outside of the US is diminished or halted, our business, financial condition and results of operations may be adversely affected, and the price of our common stock may decline.
- We may not be able to successfully develop or commercialize our product candidates if problems arise in the clinical testing and/or approval process. There is a high risk that drug discovery and development efforts might not generate successful product candidates. If the results of our clinical trials do not meet the primary efficacy endpoints, or if the top-line data from the results of our clinical trials may not ultimately meet the requirements for an NDA approval by the FDA and other regulatory authorities, the commercial prospects of our business may be harmed, and our ability to generate product revenues may be delayed or eliminated.
- Our strategy to expand our hematology and oncology pipeline on our own, or through acquisitions or in-licensing of early or late-stage products or companies, or through partnerships with pharmaceutical and biotechnology companies, as well as academic institutions and government organizations, may not be successful.
- Even if we, or any of our collaborative partners, are able to continue to commercialize our products or any product candidate that we, or they, develop, the product may become subject to unfavorable pricing regulations, unfavorable health technology assessments (HTA), 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 our products and retain experienced commercial personnel, our business will be substantially harmed.
- We are subject to stringent and evolving healthcare regulatory, 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, audits, 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 our products, or of products with which we compete, our business may be harmed.
- Unforeseen safety issues could emerge with our products 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 third-party distribution facilities for the sale of our products and potential sale of any of our product candidates. If any or all of them become subject to adverse findings from inspections or face other difficulties to operate, then the distribution of our products may be interrupted or otherwise adversely affected.

- 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.
- 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, MHRA 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 may be unable to generate revenue from the sale of such products, our potential for generating positive cash flow may be diminished, and the capital necessary to fund our operations will be increased. Additionally, approval of a drug under the accelerated drug approval program may be withdrawn or the labeled indication of the drug changed if trials fail to verify clinical benefit or do not demonstrate sufficient clinical benefit to justify the risks associated with the drug.
- 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 securing intellectual property rights and data exclusivity and other regulatory rights (such as orphan exclusivity, pediatric extensions and supplementary protection certificate) 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, partnering and commercialization activities.
- 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 our products 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 our products 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 our products 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.

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.

While we have substantially increased the size of our organization particularly in our sales force in 2021, we also implemented reductions in workforce particularly in our research and development group in 2021 and 2022. We may need to add additional qualified personnel and resources to support our commercial activities and expected growth. 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 our products and development of our other product candidates.

Our future financial performance and our ability to sustain successful commercialization of our products 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 our products, 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 a potential pandemic or global economic slowdown, could adversely affect our business and operations.

Our strategy to expand our hematology and oncology pipeline on our own, or through acquisitions or in-licensing of early or late-stage products or companies, or through partnerships with pharmaceutical and biotechnology companies, as well as academic institutions and government organizations, may not be successful.

Our business is focused on the development and commercialization of novel therapies that significantly improve the lives of patients with hematologic disorders and cancer. In this regard, we continue to pursue internal drug discovery efforts or partnerships with pharmaceutical and biotech companies, as well as academic institutions and government organizations, with the goal of identifying new product candidates to advance into clinical trials. Our discovery efforts to identify new product candidates require substantial technical, financial and human resources. These 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 trial, 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 discovery efforts, we continue to seek to broaden and diversify our product portfolio through acquisition or in-licensing of a product. This strategy is dependent on our ability to successfully identify and acquire or in-license relevant product candidates. In July 2022, we entered into a license and transition services agreement with Forma for an exclusive license to develop, manufacture and commercialize olutasidenib, a proprietary inhibitor of mIDH1, for any uses worldwide, including for the treatment of AML and other malignancies. On December 1, 2022, the FDA approved REZLIDHIA capsules for the treatment of adult patients with R/R AML with a susceptible IDH1 mutations as detected by an FDA-approved test. REZLIDHIA is our second commercial product and we believe is highly synergistic with our existing hematology-oncology focused commercial and medical affairs infrastructure. Further, in February 2024, we entered into an Asset Purchase Agreement with Blueprint to purchase certain assets comprising the right to research, develop, manufacture and commercialize GAVRETO, Blueprint's proprietary RET inhibitor of tyrosine kinase for the treatment of metastatic RET fusion-positive NSCLC and advanced thyroid cancer, in the US. Simultaneously and in connection with entering into the Asset Purchase Agreement, we also entered into certain supporting agreements with Blueprint, including a customary transition agreement, pursuant to which, during a transition period, Blueprint will transition regulatory and distribution responsibility for pralsetinib to us. On June 24, 2024, we announced the completion of the transfer of GAVRETO NDA to us, and GAVRETO became commercially available from us in the US by prescription beginning on June 27, 2024. The in-licensing and acquisition of a product 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. The success of this strategy depends partly upon our ability to identify, select and acquire or in-license promising product candidates and technologies. The process of proposing, negotiating and implementing a license or acquisition of a product candidate is lengthy and complex, and we may be unable to in-license or acquire the rights to any such products, product candidates or technologies from third parties for several reasons. We may also be unable to in-license or acquire additional relevant product candidates on acceptable terms. Further, even if we identify

acquisition or in-licensing targets, we may not be able to complete the transactions or we may determine after due diligence investigation not to pursue identified targets. Even if we succeed in our efforts to obtain rights to suitable product candidates, the success of our investments in these areas, our investment strategy will remain subject to the inherent risks associated with the development and commercialization of the product, and with the competitive business environment in which we operate.

In addition, acquisitions and in-licensing may entail numerous operational, financial and legal risks, including:

- potential failure of the due diligence process to identify significant problems, liabilities or other shortcomings or challenges of an acquired or licensed product candidate or technology, including problems, liabilities or other shortcomings or challenges with respect to intellectual property, product quality, partner disputes or issues and other legal and financial contingencies and known and unknown liabilities;
- inability to integrate the target company or in-licensed asset successfully into our existing business, inability to maintain the key business relationships of the target,
- in an in-licensing or an asset acquisition of a product that is commercially available in the market, we may not be able to successfully transition the existing patients who are dependent to the acquired or in-licensed product, or successfully enter into a reimbursement coverage contracts that the existing patients were previously dependent into, or successfully enter into a contract with contract manufacturers to continue the production of the in-licensed or acquired product;
- assumption of unknown or contingent liabilities or incurrence of unanticipated expenses;
- exposure to known and unknown liabilities, including possible intellectual property infringement claims, violations of laws, tax liabilities and commercial disputes;
- incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions;
- incurrence of large one-time expenses and acquiring intangible assets that could result in significant future amortization expense and significant write-offs;
- higher than expected acquisition and integration costs; and
- inability to maintain uniform standards, controls, procedures and policies;

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

We currently have product candidates in the clinical testing stage and may further pursue to expand our clinical testing efforts. 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 clinical development. 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 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, obtaining and maintaining reimbursement in national markets and positive recommendation from HTA bodies, maintaining regulatory compliance, manufacturing, competition and costs and expenses that may exceed current estimates. In future clinical trials, we, our partners or others may discover additional side effects and/or a 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. For example, in October 2024, we issued a Dear Healthcare Provider Letter for GAVRETO related to a new safety signal identified in an ongoing Phase 3 clinical trial of pralsetinib in first-line treatment of RET fusion-positive, metastatic NSCLC patients, being conducted by Roche. 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, we conducted a Phase 3 pivotal trial of fostamatinib in patients with wAIHA initiated in March 2019 and completed in April 2022. In June 2022, we announced top-line efficacy and safety data results of the trial, and the results did not demonstrate statistical significance in the primary efficacy endpoint of durable hemoglobin response in the overall study population. We conducted an in-depth analysis of these data to better understand differences in patient characteristics and outcomes and submitted these findings to the FDA. In October 2022, we announced that we received guidance from the FDA's review of these findings. Based on the result of the trial and the guidance from the FDA, we did not file an sNDA for this indication. Further, we may experience errors in the analysis of our clinical trial results. For example, we conducted our Phase 3 clinical trial to evaluate safety and efficacy of fostamatinib in hospitalized COVID-19 patients launched in November 2020 and completed enrollment in July 2022. We previously announced in November 2022 the top-line results did not meet statistical significance in the primary efficacy endpoint. Upon further analysis, we discovered an error by the biostatistical CRO in the application of a statistical stratification factor. After correcting for this statistical error, the primary endpoint of the study was met. However, given the end of the federal COVID-19 PHE in May 2023, and based on feedback from the FDA, DOD and other advisors regarding the program's regulatory requirements, costs, timeline and potential for success, we decided not to submit an Emergency Use Authorization (EUA) or sNDA.

Foreign regulatory requirements governing clinical trials may diverge and impose additional regulatory burdens, which may result in delays. For instance, the new EU Clinical Trials Regulation (EU) No 536/2014 (CTR) has amended the system of approval for clinical trials in the EU and has established a new clinical trials portal and database for application for authorizations, called the Clinical Trials Information System (CTIS). All ongoing clinical trials in the EU will be subject to the provisions of the CTR as of January 31, 2025. In addition, on June 18, 2024, new CTIS transparency rules came into effect, requiring scheduled publication of certain key clinical trial information

If the results of our clinical trials fail to meet the primary efficacy endpoints, or otherwise do not ultimately meet the requirements for an NDA approval by the FDA, 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 are subject 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 payors 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 may 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, certain 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 and Healthcare Reform” contained in Part I, Item 1 of our Annual Report on Form 10-K for the year ended December 31, 2023, 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 US 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 acquisition, collection, access, 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 amending 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 income from certain business initiatives.

In the US, these obligations 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 or deceptive 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 FTC has recently brought several cases alleging violations of Section 5 of the FTC Act with respect to health information, and has proposed rulemaking on a variety of privacy and data security topics. The FTC published an advance notice of proposed rulemaking in 2022 on commercial surveillance and data security, and may propose regulation concerning the ways in which companies collect, aggregate, protect, use, analyze, and retain consumer data, as well as transfer, share, sell, or otherwise monetize that data in the coming years. The FTC also finalized changes to the Health Breach Notification Rule in April 2024. Moreover, the US 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 (HIPAA), the Health Information Technology for Economic and Clinical Health Act, the Telephone Consumer Protection Act, the CAN-SPAM Act, and other laws and regulations, and continues to consider comprehensive federal privacy legislation.

In addition, state legislatures have enacted statutes to address privacy and information security issues, including the California Consumer Privacy Act of 2018 (the CCPA). For example, the CCPA, as amended by the California Privacy Rights Act (CPRA), 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 (as consumers, business contacts and employees), and authorizes potentially severe statutory damages and creates a private right of action for certain data security breaches. The CCPA also requires businesses subject to the law to provide disclosures to California residents and to provide them with rights with respect to their personal information, including the right to opt out of the sale of such information. Moreover, the CPRA, among other things, impose requirements relating to data minimization and correction, and gives California residents additional rights over their personal information, including the right to opt-out of the use of their personal information in online behavioral advertising and to opt-out of certain types of consumer profiling. The CPRA also provides for penalties for CPRA violations concerning California residents under the age of 16, and establishes a new California Privacy Protection Agency to implement and enforce the law. Although there are limited exemptions for clinical trial and other research-related data under the CCPA, the CCPA could impact our business depending on how it 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.

Multiple other states have followed California and enacted comprehensive privacy laws, or are considering similar legislation. While these new laws and proposals generally include exemptions for HIPAA-covered protected health information and clinical trial data, they add layers of complexity to compliance in the US market, and could increase our compliance costs and adversely affect our business. Moreover, some states have enacted laws specific to health data privacy, which may cause additional compliance costs such as the Washington My Health My Data Act and Nevada’s Consumer Health Data Privacy Law. States, such as Colorado, Utah and California, have passed or are considering legislation or regulation governing the development or use of artificial intelligence technologies, supplementing the existing consumer protection, FDA and other regulatory guidance that may apply to the use of AI technologies in our business, and which may impact our use of technology. Moreover, 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.

Laws and regulations relating to privacy, data protection, consumer protection, AI and information security are evolving and subject to potentially differing interpretations. These requirements may be interpreted and applied in a manner that varies from one jurisdiction to another and/or may conflict with other laws or regulations. New laws and regulations 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 US may implicate foreign data protection laws, including those 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, in the EU, the collection, use, disclosure, transfer and other processing of personal data (i.e., data which identifies an individual or from which an individual is identifiable) is governed by the EU General Data Protection Regulation 2016/679 (the EU GDPR), which came into direct effect in all EU Member States on and from May 25, 2018. The UK has implemented the EU GDPR as the UK GDPR which sits alongside the UK Data Protection Act 2018 (the UK GDPR, together with the EU GDPR, the GDPR). The GDPR has direct effect where an entity is established in the European Economic Area (EEA) or the UK (as applicable) and has extraterritorial effect, including where an entity established outside of the EEA or the UK processes personal data in relation to offering goods or services to individuals in the EEA and/or the UK or monitoring their behavior.

The GDPR imposes obligations on controllers, including, among others:

- accountability and transparency requirements, requiring controllers to demonstrate and record compliance with the GDPR and to provide more detailed information to data subjects regarding processing of their personal data;

- requirements to process personal data lawfully including specific requirements for obtaining valid consent where consent is the lawful basis for processing;

- obligations to consider data protection when any new products or services are developed and designed (including e.g., to limit the amount of personal data processed);

- obligations to comply with data protection rights of data subjects including a right: (i) of access to, erasure of, or rectification of personal data, (ii) to restriction of processing or to withdraw consent to processing, and (iii) to object to processing or to ask for a copy of personal data to be provided to a third party; and

- an obligation to report personal data breaches to: (i) the data supervisory authority without undue delay (and no later than 72 hours after discovering the personal data breach, where feasible), unless the personal data breach is unlikely to result in a risk to the data subjects' rights and freedoms; and (ii) to affected data subjects, where the personal data breach is likely to result in a high risk to their rights and freedoms.

In addition, the EU GDPR prohibits the international transfer of personal data from the EEA to jurisdictions that the European Commission does not recognize as having 'adequate' data protection laws unless a data transfer mechanism has been put in place or a derogation under the EU GDPR can be relied on. In July 2020, the Court of Justice of the EU (CJEU) in its Schrems II judgement limited how organizations could lawfully transfer personal data from the EEA to the US by invalidating the EU-US Privacy Shield for purposes of international transfers and imposing further restrictions on the use of standard contractual clauses (EU SCCs), including a requirement for companies to carry out a transfer privacy impact assessment (TIAs). A TIA, among other things, assesses laws governing access to personal data in the recipient country and considers whether supplementary measures that provide privacy protections additional to those provided under EU SCCs will need to be implemented to ensure an 'essentially equivalent' level of data protection to that afforded in the EEA.

On October 7, 2022, US President Biden introduced an Executive Order to facilitate a new Trans-Atlantic Data Privacy Framework (DPF) and on July 10, 2023, the European Commission adopted its Final Implementing Decision granting the US adequacy (Adequacy Decision) for EU-US transfers of personal data for entities self-certified to the

DPF. Entities relying on EU SCCs for transfers to the US. are also able to rely on the analysis in the Adequacy Decision as support for their TIA regarding the equivalence of US national security safeguards and redress. This may have implications for our cross-border data flows and has and may in the future result in increased compliance costs.

The UK GDPR also imposes similar restrictions on transfers of personal data from the UK to jurisdictions that the UK Government does not consider adequate, including the US. The UK Government has published its own form of the EU SCCs, known as the International Data Transfer Agreement and an International Data Transfer Addendum to the new EU SCCs. The UK Information Commissioner's Office has also published its version of the TIA and guidance on international transfers, although entities may choose to adopt either the EU or UK style TIA. Further, on September 21, 2023, the UK Secretary of State for Science, Innovation and Technology established a UK-US data bridge (i.e., a UK adequacy decision) and adopted UK regulations to implement the UK-US data bridge (UK Adequacy Regulations). The UK Adequacy Regulations have now been passed in the UK Parliament, and personal data may be transferred from the UK under the UK-US data bridge through the UK extension to the DPF, from October 12, 2023, to organizations self-certified under the DPF.

The GDPR imposes fines for serious breaches of up to the higher of 4% of the organization's annual worldwide turnover or €20 million (under the EU GDPR) or £17.5 million (under the UK GDPR). The GDPR identifies a list of points to consider when determining the level of fines for data supervisory authorities to impose (including the nature, gravity and duration of the infringement). Data subjects also have a right to compensation, as a result of an organization's breach of the GDPR which has affected them, for financial or non-financial losses (e.g., distress).

Privacy and data protection compliance has and may in the future require substantial amendments to our procedures and policies and the changes could adversely impact our business by increasing operational and compliance costs or impact business practices. Further, there is a risk that the amended policies and procedures will not be implemented correctly or that individuals within the business will not be fully compliant with the new procedures. If there are breaches of these measures, we could face significant litigation, government investigations, administrative and monetary sanctions as well as reputational damage which may have a material adverse effect on our operations, financial condition and prospects. There is a risk that we could be impacted by a cybersecurity incident that results in loss or unauthorized disclosure of personal data, potentially resulting in us facing harms similar to those described above.

Additionally, other countries outside of Europe have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, with 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 their right 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, cybersecurity requirements are laid down in various laws in the EU and the UK, the key ones being: (i) the GDPR (as discussed in detail above), which requires controllers and processors to implement appropriate technical and organizational measures to safeguard personal data to a level of security appropriate to the data protection risk; and (ii) the UK Network and Information Systems Regulation 2018 (NIS

Regulations), and the EU Network and Information Systems Security 2 Directive (NISD2) as implemented into EU Member State law.

The GDPR does not provide for a specific set of cybersecurity requirements or measures to be implemented, but rather requires a controller or processor to implement appropriate cyber and data security measures in accordance with the then-current risk, the state of the art, the costs of implementation and the nature, scope, context and purposes of the processing. The GDPR however does explicitly require that controllers notify personal data breaches, within the meaning of the GDPR, without undue delay and in any event within 72 hours after becoming aware of it, to the relevant data protection supervisory authority, unless the breach is unlikely to result in a risk to the rights and freedoms of individuals. In addition, controllers are required to notify the individuals concerned of any personal data breach, without undue delay, when the personal data breach is likely to result in a high risk to the rights and freedoms of individuals. Processors are required to notify the controller without undue delay after becoming aware of a personal data breach.

In the UK, the NIS Regulations apply to 'operators of essential services' (OES) and 'relevant digital service providers' (RDSP) and following the UK General Election in July 2024, the new UK Government has announced it intends to introduce a Cyber Security and Resilience Bill to the UK Parliament. The NIS Regulations require that appropriate and proportionate technical and organizational measures are implemented to manage the risk of network and information systems, and impose requirements related to incident handling and notification in relation to incidents with significant disruptive effect. Under the NIS Regulations, the UK's data protection supervisory authority, the Information Commissioner's Office, may issue fines of up to £17 million and take other action following non-compliance.

In the EU, more stringent cybersecurity and incident reporting requirements are imposed on 'essential' and 'important' entities, which include ICT managed service providers (MSP), cloud service providers as well as entities carrying out research and development activities of medicinal products, and certain specific medical device manufacturers. Our entities may be in scope of the NISD2 where they qualify as a MSP, cloud provider, R&D entity and/or medical device manufacturer within the meaning of NISD2 and offer those services in the EU.

The NISD2 empowers the EU Member States to define all rules regarding penalties applicable to infringements, provided that they are effective, proportionate, and dissuasive. NISD2 states that any maximum fine which national implementing law provides for should at least be set at €10 million or 2% of total worldwide turnover, whichever is higher, where essential entities are concerned. Other sanctions may include (i) a temporary suspension to provide services in the EU (by suspending relevant authorizations/certifications); (ii) an order to make public certain elements of the infringement and/or inform customers; and (iii) injunctions to immediately cease infringing conduct. Importantly, NISD2 also provides that senior members of staff can be held personally liable, and face administrative fines or be temporarily suspended from exercising managerial functions at the legal representative or chief executive officer level.

In addition, the EU Critical Entities Resilience Directive (CER) is aimed at strengthening the resilience of 'critical infrastructure' against specific threats including cyber incidents, natural hazards, terrorist attacks, insider threats, and sabotage. The scope of CER includes entities designated as 'critical' under CER and includes (among other things) the health sector and the manufacturers of medical devices as 'essential services.' The CER imposes cybersecurity and resilience requirements in particular in relation to incidents with so-called 'significant disruptive effects' – which are incidents that are able to significantly impact the continuation of the critical infrastructure service offering in the EU. Requirements include to: (i) identify relevant risks that may significantly disrupt the provision of essential services (i.e., pursuant to a risk assessment); (ii) take appropriate and proportionate technical, security and organizational measures to ensure resilience (i.e., based on the outcome of the risk assessment); and (iii) notify disruptive incidents to the competent authorities within 24 hours after becoming aware of an incident. The CER is enforceable on a national EU Member State level by the competent authorities, and allows EU Member States to set penalties as long as they are effective, proportionate, and dissuasive. Our entities may be in scope of the CER where they qualify as critical entities within the meaning of CER.

In the EU, a number of new laws related to digital data and AI have also recently entered into force, are expected to enter into force in the foreseeable future, or have been proposed and are being considered. We are still assessing the scope of application, impact, and risk of these recent EU laws on our business, and will continue to assess this moving forward, including for example: (i) the EU's Data Act– came into force as of December 13, 2023 which seeks to, among other things regulate the use of, and access to, data generated through connected (or Internet-of-Things)

devices and introduces a new means for public sector bodies to access, use and re-use private sector data; and (ii) the proposed European Health Data Space Regulation (EHDS) – expected to be agreed by end of 2024 – which seeks to , among other things, provide individuals with more control over their electronic health data (EHD), enable cross-border sharing of EHD between national EU healthcare systems and facilitate the sharing of EHD for secondary research purposes.

The EU has also developed a standalone law to govern the offering and use of AI systems in the EU (the AI Act) which was published in the Official Journal of the European Union on July 12, 2024 and entered into force on August 1, 2024. The AI Act imposes regulatory requirements on AI system providers, deployers, importers, distributors, and users of AI systems, in accordance with the level of risk involved with the AI system ("unacceptable", "high", "limited", and "minimal" risk). Unacceptable-risk AI systems are banned from being offered and used in the EU, and high-risk AI systems (which include AI used as part of medical devices in certain instances) are subject to a set of regulatory requirements under the AI Act including to establish quality and post-marketing monitoring and risk assessment systems, requirements related to the training of AI systems and training data, and requirements related to human oversight. Limited-risk AI systems are subject mainly to transparency requirements only and minimal-risk AI systems are not subject to obligations under the AI Act. General-purpose AI systems have also been made subject to a number of requirements – mostly akin to the requirements that apply to high-risk AI systems under the AI Act.

The AI Act will enter into application (i.e., be enforceable) in a gradual manner – depending on the regulatory requirement in question, and ranging anywhere from 6 to 36 months following adoption. Non-compliance with the AI Act may be subject to regulatory fines of up to 7% of annual worldwide turnover. In parallel, the EU has proposed revisions to the EU Product Liability Directive and has introduced a new EU AI Liability Directive to facilitate claims for damages brought by EU users of AI systems.

The UK had adopted a "soft law" approach to AI regulation meaning that until now it has not adopted formal legislation to regulate AI but has adopted soft law guidelines in the form of a White Paper and will pursue enforcement through the sector-specific regulators. However, following the UK General Election in July 2024, the new UK Government has announced it intends to introduce an AI Bill to the UK Parliament.

Further, many jurisdictions impose mandatory clinical trial information obligations on sponsors. In the EU, such obligations arise under the Transparency Regulation No 1049/ 2001, EMA Policy 0043, EMA Policy 0070 and the Clinical Trials Regulation No 536/2014 (which the UK has not implemented, as the law entered into force following the UK's exist from the EU), 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 EU-based parties the right to submit an access to documents request to the EMA for information included in the MAA 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 manufacturer-sponsored patient assistance program that helps financially needy patients in the US access our therapies. This type of program has become the subject of enforcement scrutiny in recent years. For example, some pharmaceutical manufacturers have been named in lawsuits challenging the legality of their patient assistance programs under a variety of federal and state laws. In addition, certain state and federal enforcement authorities continue to pursue investigations and enter into settlements related to manufacturers' support of patient assistance programs, and members of Congress have also initiated inquiries on topics that include, for example, manufacturer-sponsored patient assistance programs, co-payment assistance programs, and manufacturer contributions to independent charitable patient assistance programs. Moreover, the DHHS, Office of the Inspector General continues to publish advisory opinions and other agency guidance on the topic of patient assistance, which reflects the government's continued scrutiny of manufacturer sponsored or supported patient assistance programs. Numerous organizations, including pharmaceutical manufacturers, have been subject to ongoing litigation, enforcement activities and settlements related to their patient support programs 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 be proposed that would establish requirements or restrictions with respect to these programs and/or support that would affect pharmaceutical manufacturers.

Our patient assistance program could become the target of similar inquiries, litigation, enforcement, and/or legislative proposals. 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. 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 our products, or of products with which we compete, our business may be harmed.

Under the Federal Food, Drug and Cosmetic Act (FDCA), the FDA can approve an 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 and 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 our products.

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 FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (referred to as 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 our products or products with which it competes, our business would be harmed.

In June 2022, we received a notice letter regarding an ANDA submitted to the FDA by Annora, requesting approval to market a generic version of TAVALISSE. The notice letter included a Paragraph IV certification with respect to our US Patent Nos. 7,449,458; 8,263,122; 8,652,492; 8,771,648 and 8,951,504, which are listed in the Orange Book. The notice letter asserts that these patents will not be infringed by Annora's proposed product, are invalid and/or are unenforceable. Annora's notice letter does not provide a Paragraph IV certification against our other patents listed in the Orange Book. On July 25, 2022, we filed a lawsuit in the US District Court for the District of New Jersey against Annora and its affiliates, Hetero Labs Ltd., and Hetero USA, Inc., for infringement of our US patents identified in Annora's Paragraph IV certification. On September 21, 2022, Annora and its affiliates answered and counterclaimed for declaratory judgment of non-infringement and invalidity of the '458, '122, '492, '648, and '504 patents. We filed an answer to Annora's counterclaims on October 12, 2022. Annora served invalidity and non-infringement contentions on December 31, 2022. We filed an answer to Annora's invalidity and non-infringement contentions in March 2023. Litigation continues, and no trial date is currently set. We intend to vigorously enforce and defend our intellectual property related to TAVALISSE. We cannot be assured that such lawsuit will prevent the introduction of a generic version of TAVALISSE for any particular length of time, or at all. If an ANDA from Annora or any other generic manufacturer is approved, and a generic version of TAVALISSE is introduced, whether following the expiration of our patents, the invalidation of our patents as a result of any litigation, or the determination that the proposed generic product does not infringe on our patents, our sales of TAVALISSE would be adversely affected. In addition, we cannot predict

what additional ANDAs could be filed by Annora or other potential generic competitors requesting approval to market generic forms of our products, which would require us to incur significant additional expense and result in distraction for our management team, and if approved, result in significant decreases in the revenue derived from sales of our marketed products and thereby materially harm our business and financial condition.

Unforeseen safety issues could emerge with our products 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 our products 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 our products after approval:

- regulatory authorities may require the addition of labeling statements, specific warnings, contraindications, Dear Healthcare Provider letters, press releases, field alerts, or other communications containing warnings or other safety information about our products to physicians and pharmacies;
- regulatory authorities may withdraw their approval of the product and require us to take our approved drugs off the market or suspend their commercialization until the identified issues have been satisfactorily addressed;
- 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 (REMS);
- we may have additional limitations on how we promote our drugs;
- third-party payors may limit coverage or reimbursement for our products;
- sales of our products 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 our products and could substantially increase our operating costs and expenses, which in turn could delay or prevent us from generating significant revenue from sale of our products. For example, in October 2024, we issued a Dear Healthcare Provider letter related to a new safety signal for GAVRETO. The letter advises healthcare providers to apply certain measures to protect patient safety, including enhanced ongoing monitoring for signs and symptoms of infection as well as guidance for withholding treatment to patients in the presence of active infection. This and other communications containing warnings or other safety information to physicians and pharmacies, or required updates to labeling statements, including specific warnings or contradictions, could limit the commercial success of GAVRETO or any of our other drug products.

Side effects and toxicities associated with our products, as well as the warnings, precautions and requirements listed in the prescribing information for our products, could affect the willingness of physicians to prescribe, and patients to utilize, our products and thus harm commercial sales of our products. For example, for REZLIDHIA, the FDA-approved label contains a boxed warning describing the risk of differentiation syndrome, which can be fatal, in patients receiving the drug. This and other restrictions could limit the commercial success of the product.

If a safety issue emerges post-approval, we may become subject to costly product liability litigation by our customers, their patients or payors. 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 our products 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.

Our business could be materially and adversely affected by pandemics as a result of their potential 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.

Pandemics may result in extended travel and other restrictions in order to reduce the spread of diseases. Government measures taken in response to pandemics could have a significant impact, both direct and indirect, on our business and commerce, as significant reductions in business related activities may occur, supply chains may be disrupted, and manufacturing and clinical development activities may be curtailed or suspended.

For example, during the COVID-19 pandemic, we observed reduced patient-doctor interactions and our representatives had fewer visits with health care providers, which negatively affected our product sales. Physicians with practices severely impacted by the COVID-19 pandemic, or a pandemic occurring in the future, and who currently prescribe our products, may eventually decide to close their independent practices and join a larger medical organization with a practice that does not prescribe our products. Additionally, a pandemic, including COVID-19 or any resurgence thereof, may impact commercial-related activities, such as our marketing programs, speaker bureaus, and market access initiatives which may be required to be conducted virtually, delayed or cancelled, all of which occurred as a result of the COVID-19 pandemic. During the COVID-19 pandemic, we had to deploy resources to enable our field-based employees to continue to engage with health care providers in hybrid virtual and in-person interactions, which may be required in the event a pandemic occurs in the future.

With respect to clinical development, in response to the COVID-19 pandemic, we took measures to implement remote and virtual approaches, including remote patient monitoring where possible and working with our investigators for appropriate care of these patients in a safe manner. Due to the effects of COVID-19 pandemic, we experienced a number of our clinical trial investigators either paused, postponed or delayed new patient enrollment and restricted site visits of existing patients enrolled. In the event that a global pandemic, or a resurgence of the COVID-19 pandemic, occurs in the future, we may need to make decisions on a country-by-country basis to minimize risk to the patients and clinical trial sites. We may 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. We experienced slower than anticipated enrollment in some of our clinical trials due to adverse effects of COVID-19 pandemic, and in the future, we may experience adverse impacts of a global pandemic on our clinical trials, including the timing thereof, or our ability to continue to treat patients enrolled in our trials, enroll and assess new patients, supply study drugs and obtain complete data points in accordance with study protocol.

Pandemics may cause significant disruption in the supply chain for our commercial products. We 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. While 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 our products and to remain informed of any challenges within our supply chain, we may face disruptions to our supply chain and operations, and associated delays in the manufacturing and supply of our products. Such supply disruptions would adversely impact our ability to generate sales of and revenues from our products and our business, financial condition, results of operations and growth prospects could be adversely affected.

Pandemics may affect our collaboration and licensing partners for the commercialization of our products globally, as well as our ability to advance our various clinical stage programs. We cannot predict the impact of such disruptions on our partners' ability to advance commercialization of our products 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 pandemics. For example, in response to the COVID-19 pandemic, the FDA delayed inspections and evaluations of certain drug manufacturing facilities and clinical research sites We cannot predict whether, and when, health regulatory agencies will decide to pause or resume inspections due to pandemics. 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, as seen in the COVID-19 pandemic, pandemics could result in a significant disruption of global financial markets. We could experience an inability to access additional capital or 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, or we may not be able to meet the requirements under our Credit and Security Agreement (Credit Agreement) with MidCap Financial Trust (MidCap). While we expect pandemics to adversely affect our business, financial condition, results of operations and growth prospects in the future periods, 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 circumstances that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration and severity of pandemics, travel restrictions, quarantines, social distancing and business closure requirements in the US and other countries, and the effectiveness of actions taken globally to contain and treat diseases. To the extent pandemics 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.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in the US, we could be subject to additional rebate or discount 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 CMS, the 340B Drug Pricing Program, as administered by the Health Resources and Services Administration, and other federal and state government drug pricing programs in the US, 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 payors and/or required covered entities 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 metrics 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. Most recently, in September 2024, CMS published a final rule that included significant revisions to certain Medicaid Drug Rebate Program provisions, including, but not limited to: (i) new definitions for key terms under the Medicaid Drug Rebate Program, such as "covered outpatient drug" and "market date"; (ii) revised processes for identifying drug misclassifications, as well as additional penalties that can be imposed against manufacturers in connection with such misclassifications; and (iii) a new 12-quarter time limit for manufacturers to initiate disputes, hearing requests, and audits for state-invoiced rebate amounts. 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 DHHS, Office of Inspector General and other governmental enforcement and administrative bodies have increased their focus, including through recent enforcement actions against manufacturers, on pricing requirements for products, including, but not limited to the methodologies used by manufacturers to calculate average manufacturer price and best price 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 payors. 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 US government or response 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.

Finally, we may be affected by developments relating to the 340B Drug Pricing Program (340B Program). Recently, multiple manufacturers have implemented policies to reduce diversion and inappropriate claims for discounts and rebates by in-house and contract pharmacies affiliated with 340B-eligible entities. The DHHS sent several of these manufacturers' letters claiming that the policies violate the 340B statute and referring the manufacturers for potential enforcement action. Manufacturers challenged these letters in federal court, and the US Court of Appeals for the Third Circuit and the District of Columbia Circuit have ruled in favor of several manufacturers, finding that the policies were consistent with the 340B statute. Multiple states have recently enacted laws that require manufacturers to ship 340B drugs to certain contract pharmacies and impose various civil and criminal penalties on manufacturers that do not comply. These laws have been challenged in federal court and many of the cases are pending. In March 2024, the US Court of Appeals for the Eight Circuit upheld the Arkansas law prohibiting drug makers for restricting 340B drug discounts for providers using contract pharmacies, and plaintiffs have filed a writ of certiorari with the Supreme Court, which is pending. DHHS also issued a final rule on procedures for the 340B program's administrative dispute resolution process in April 2024. It is unclear how the other pending litigation, recent and proposed legislation, or future administrative action relating to the 340B program will impact our business.

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, third-party 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, third-party 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;
- any additional support that may be required to administer the treatment to patients;
- 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, third-party 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, 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 commercialization of our products. We may seek another collaborator or licensee in the future for further clinical development and commercialization of our products, 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 commercialization of our products 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 commercialization of our products, 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 our products. 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 US and worldwide resulting from a global pandemic and the global tensions arising from the Russia-Ukraine war and the Hamas-Israel war. 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 the 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 includes certain covenants that may restrict our business, 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.

We entered into a Credit Agreement with MidCap on September 27, 2019, amended on March 29, 2021, February 11, 2022, July 27, 2022, and April 11, 2024. The Credit Agreement provides for a $60.0 million term loan credit facility. As of September 30, 2024, the outstanding principal balance of the loan was $60.0 million, and no remaining funds were available under the term loan credit facility. 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. See “Note 10 – Debt” 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.

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

Our distribution operations for the sale of our products are 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. Further, climate change may increase both the frequency and severity of extreme weather conditions and natural disasters, which may affect our business operations. If we encounter difficulties with any of our distribution facilities, whether due to the potential future impacts of a global 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;
- potential future impacts, if any, including a global 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 products 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. We make estimates for provisions for sales discounts, returns and allowances. Our estimates are based on available customer and payor data received from the specialty pharmacies and distributors, as well as third party market research data. In part, our estimates are dependent on our distribution channel and payor mix. If actual results in the future vary from our estimates, we adjust these estimates, which would affect our net product revenue and earnings in the period such variances become known. 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 our products and product candidates we licensed to our collaboration partners

We do not and will not have access to all information regarding our product 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 our collaboration partners. In addition, we have confidentiality obligations under our respective agreements with our collaboration partners. Thus, our ability to keep our shareholders informed about the status of our products and other product candidates will be limited by the degree to which our collaboration partners keep us informed and allows us to disclose such information to the public. If our collaboration partners fail to keep us informed about commercialization efforts related to our products, 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 our products in the US, 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 secure patent and regulatory protection;
- our ability to secure a favorable price or a positive HTA assessment;
- potential future impacts, if any, of a global 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.*

For the nine months ended September 30, 2024, we recognized income from operations of $7.5 million primarily due to higher net product sales and collaboration revenues, partially offset by our operating expenses. Historically, we have 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 and costs of our ongoing commercial efforts. Although we recognized income from operations for the current period, there can be no assurance that we will generate annual operating income in the foreseeable future. Currently, our potential sources of revenues include sales of our products, and upfront payments as well as milestone and royalty payments pursuant to our collaboration arrangements, all of which may never materialize if sales of our products decline or if our collaboration partners 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, 2024, we had an accumulated deficit of approximately $1.4 billion. The extent of our future losses or profitability, if any, 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 may seek another collaborator or licensee in the future for clinical development and commercialization of our products, 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 US issued patent that has expiration date of September 2031, olutasidenib is covered as a composition of matter in a US issued patent that has an expected expiration date of December 2036, after taking into account patent term extension rules, and pralsetinib is covered as a composition of matter in a US issued patent that has an expiration date in November 2036 and subject to extensions.

In the future, our patent position might be highly uncertain and involve complex legal and factual questions , and the cost to defend may also be significant. For example, we may be involved in post-grant proceedings before the US 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 US Patent and Trademark Office or non-US patent offices. Any successful opposition to our patents could deprive us of exclusive rights necessary for the successful commercialization of our products 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.

An adverse outcome may allow third parties to use our intellectual property without a license and/or allow third parties to introduce generic and other competing products, any of which would negatively impact our business. For example, in June 2022, we received a notice letter from Annora advising that it has filed an ANDA with the FDA for a generic version of TAVALISSE and asserting that certain patents related to TAVALISSE that are listed in the Orange Book will not be infringed by Annora's proposed product, are invalid and/or are unenforceable. In July 2022, we filed a lawsuit in the US District Court for the District of New Jersey against Annora and its subsidiaries for infringement of those US patents. In September 2022, Annora and its subsidiaries answered and counterclaimed for declaratory judgment of non-infringement and invalidity of those patents. We filed an answer to Annora's counterclaims on October 12, 2022. Annora served invalidity and non-infringement contentions on December 31, 2022. We filed an answer to Annora's invalidity and non-infringement contentions in March 2023. Litigation continues, and no trial date is currently set. We intend to vigorously enforce and defend our intellectual property rights related to TAVALISSE. Should Annora or any other third parties receive FDA approval of an ANDA for a generic version of fostamatinib or a 505(b)(2) NDA with respect to fostamatinib, and if our patents covering fostamatinib were held to be invalid (or if such competing generic versions of fostamatinib were found to not infringe our patents), then they could introduce generic versions of fostamatinib or other such 505(b)(2) products before our patents expire, and the resulting competition would negatively affect our business, financial condition and results of operations. Please also see the risk factor entitled, "If manufacturers obtain approval for generic versions of our products, or of products with which we compete, our business may be harmed." In the future, there might be other claims that are subject to substantial uncertainties and

unascertainable damages or other remedies, and the cost to defend may also be significant.

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 that:

- we were the first to make the inventions covered by each of our pending patent applications;
- 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;
- we will obtain a supplementary protection certificate that will extend the protection afforded by the patent to the product with a marketing authorization; 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 US government resources.

The US 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, partnering and commercialization activities.

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 US 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 (NOLs) 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 Cuts and Jobs Act (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 NOLs 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 Assembly Bill 85, our California NOL carryforwards are suspended for tax years 2020, 2021, and 2022, but the period to use these carryovers was extended. In June 2024, California Senate Bill 167 was signed into law which suspends NOL deductions for tax years beginning on or after January 1, 2024 and before January 1, 2027 for taxpayers with net business income or modified adjusted gross income of at least $1.0 million for the tax year. The legislation also limits the aggregate use of otherwise allowable business credits to $5.0 million for each tax year beginning on or after January 1, 2024 but before January 1, 2027 (except for certain credits not subject to the limitation). Further, the Tax Act requires the taxpayers to capitalize Research and Experimental (R&E) expenditures under Section 174 of the Internal Revenue Code, as amended (Code), effective for taxable years beginning after December 31, 2021, which will reduce our NOLs beginning in 2022. R&E expenditures attributable to US-based research must be amortized over a period of 5 years and R&E expenditures attributable to research conducted outside of the US must be amortized over a period of 15 years.

In addition, utilization of NOLs 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 Code and similar state provisions, which may result in the expiration of NOLs 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 NOLs 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 NOLs 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 NOLs is conditioned upon us achieving profitability and generating US 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 current collaborations including Lilly, Grifols, Kissei, Medison, Knight, BerGenBio, and Daiichi. Under several 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 recognized material amount of revenue from royalties for the commercial sale of drugs, and we do not know when we will be able to generate such meaningful revenue in the future.

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 our products in which there are existing therapies and drug candidates in development for the treatment of hematologic disorders and cancer that may be alternative therapies to our products. 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 payors. 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 US 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 versions of our products 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 developing 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 US 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;
- obtain access to manufacturing resources of the sufficient standard and scale;
- enter commercialization agreements for our new drug compounds; and
- obtain and maintain appropriate reimbursement price and positive recommendations by HTA bodies.

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 our products in the US;
- 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;

- the announcement of regulatory applications, such as Annora's ANDA, seeking approval of generic versions of our marketed products;
- 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 US 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.

We completed a reverse stock split of our shares of common stock, which may reduce and may limit the market trading liquidity of the shares due to the reduced number of shares outstanding and may potentially have an anti-takeover effect.*

We completed a reverse stock split of our common stock by a ratio of 1-for-10 effective June 27, 2024. The primary objective of the reverse stock split was to attempt to raise the per share trading price of our common stock. We believe that a low per share market price of our common stock impairs our marketability to, and acceptance by, institutional investors and other members of the investing public and creates a negative impression of us. Among other benefits, the effectuation of the reverse stock split seeks to help us maintain compliance with the minimum bid continued listing requirement of $1.00 per share required to maintain continued listing on The Nasdaq Global Select Market (the Bid Price Requirement). Prior to us effecting a reverse stock split, the closing bid price of our common stock at certain periods fell below $1.00 per share for 30 consecutive trading days. We received deficiency letters from the Listing Qualifications Department of Nasdaq on November 22, 2022 and November 27, 2023, notifying us that, for 30 consecutive business days, the bid price for our common stock had closed below the Bid Price Requirement. We received notification from the Listing Department of Nasdaq on January 5, 2023 and December 12, 2023 that we had regained our compliance with the Bid Price Requirement because the closing price of our common stock closed at $1.00 or more for over 10 consecutive days. Although we regained compliance with the Nasdaq Bid Price Requirement, in the future, Nasdaq may initiate a delisting process with a notification letter if we were to again fall out of compliance. If we were to receive such a notification, we would be afforded a grace period of 180 calendar days to regain compliance with the Bid Price Requirement. In order to regain compliance, shares of our common stock would need to maintain a minimum closing bid price of at least $1.00 per share for a minimum of 10 consecutive trading days. Additionally, we may be unable to meet other applicable Nasdaq listing requirements, including maintaining minimum levels of stockholders' equity or market values of our common stock in which case, our common stock could be delisted. If our common stock were to be delisted, the liquidity of our common stock would be adversely affected and the market price of our common stock could decrease.

Reducing the number of outstanding shares of our common stock through the reverse stock split increased the per share trading price of our common stock. However, there is no assurance that:

- the market price per share of our common stock after the reverse stock split will rise in proportion to the reduction in the number of shares outstanding before the reverse stock split;
- the reverse stock split will result in a per-share price that would attract brokers and investors who do not trade in lower-priced stocks;
- the reverse stock split will result in a per-share price that will increase our ability to attract and retain employees and other service providers; or

- the reverse stock split will promote greater liquidity for our stockholders with respect to their shares.

In addition, the reverse stock split reduced the number of outstanding shares of our common stock without reducing the authorized number of shares of our common stock. Therefore, the number of shares of our common stock that are authorized and unissued has increased relative to the number of issued and outstanding shares of our common stock following the reverse stock split. Our Board of Directors may authorize the issuance of the remaining authorized and unissued shares without further stockholder action for a variety of purposes, except as such stockholder approval may be required in particular cases by our Amended and Restated Certificate of Incorporation, applicable law or the rules of any stock exchange on which our securities may then be listed. The issuance of additional shares would be dilutive to our existing stockholders and may cause a decline in the trading price of our common stock. The issuance of authorized but unissued shares of common stock could be used to deter a potential takeover of us that may otherwise be beneficial to stockholders by diluting the shares held by a potential suitor or issuing shares to a stockholder that will vote in accordance with the our Board of Director's desires. A takeover may be beneficial to independent stockholders because, among other reasons, a potential suitor may offer such stockholders a premium for their shares of stock compared to the then-existing market price. We do not have any plans or proposals to adopt provisions or enter into agreements that may have material anti-takeover consequences.

The market price of our common stock is based on our performance and other factors, some of which are unrelated to the number of shares outstanding. If the market price of our common stock declines, the percentage decline as an absolute number and as a percentage of our overall market capitalization may be greater than would occur in the absence of the reverse stock split.

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

Following the result of a referendum in 2016, the UK left the EU 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 to 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). The UK Government and the EU recently adopted a new agreement, the "Windsor Framework" which will replace the Northern Ireland Protocol. According to the Windsor Framework, medicinal products intended for the UK market including Northern Ireland will be authorized by the MHRA, and will bear a "UK only" label. This means that Medicinal products placed on the market in Northern Ireland will no longer need to be compliant with EU law. These new measures will be implemented from January 1, 2025.

A separate marketing authorization will be required to market drugs in Great Britain. The MHRA has launched the Innovative Licensing and Access Pathway (ILAP), a new accelerated assessment procedure for marketing authorization applications facilitating the interaction with pricing authorities and HTA bodies and aiming to enable companies to enter the UK market faster. On January 1, 2024, the MHRA launched a new International Recognition Procedure for Great Britain (England, Scotland and Wales) marketing authorization applications whereby the MHRA will, when considering such applications, recognize the approval of medicines by trusted reference regulators in Australia, Canada, Switzerland, Singapore, Japan, United States and EU following its own abbreviated assessment. 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 as 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 conditions that are not currently designated as orphan conditions in the EU will be designated as such in Great Britain.

In April 2023, the European Commission adopted a wide ranging proposal for a new Directive and a new Regulation. If made into law, this proposal will revise and replace the existing general pharmaceutical legislation. This change will likely result in significant changes to the pharmaceutical industry. In particular, it is expected that the new Directive and Regulations will, if made into law, affect the duration of the period of regulatory protection afforded to medicinal products including regulatory data protection (also called “data exclusivity”), marketing exclusivity afforded to orphan medicinal products, as well as the conditions of eligibility to the orphan designation.

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 with competing pharmaceutical or biotechnology companies, any of which may have a detrimental impact on our research objectives and could have an adverse effect on our business, financial condition and results of operations.

While we have a strong compliance process in place to ensure we are complying with all requirements of law, our consulting or advisory contracts with our scientific consultants and advisors may be scrutinized under the Anti-Kickback Statute, the UK Bribery Act 2010, and other similar national and state-level legislation, which prohibit, among other things, companies from offering or paying anything of value as remuneration for ordering, purchasing, or

recommending the ordering or purchasing of pharmaceutical and biological products that may be paid for, in whole or in part, by Medicare, Medicaid, or another federal healthcare program. Although there are several statutory exceptions and regulatory safe harbors that may protect these arrangements from prosecution or regulatory sanctions, our consulting and advising contracts may be subject to scrutiny if they do not fit squarely within an available exception or safe harbor.

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 dependent upon information technology systems, infrastructure, and data to operate our business. While we believe our cybersecurity measures are adequate, our cybersecurity risk management, strategy and governance may be found to be inadequate that could harm our business. We 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 breakdowns, 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 operate large-scale and complex automated attacks, including on companies within the healthcare industry. As the cyber-threat landscape evolves, these threats are likely growing in frequency, sophistication and intensity and are 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. Such attacks, such as in the case of a ransomware attack, also may interfere with our ability to continue to operate and may result in delays and shortcomings due to an attack that may encrypt our or our service providers' or partners' systems unusable. Additionally, 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 trial 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 US 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. Notably, on July 26, 2023, the SEC adopted a final rule on cybersecurity risk management, strategy, governance and incident disclosure (SEC Cyber Rule). The SEC Cyber Rule requires public companies to make current disclosures about material cybersecurity incidents as well as annual disclosures of material information about their cybersecurity risk management, strategy and governance. The SEC Cyber Rule became effective on September 5, 2023. 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 our 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. We have an Open Market Sale Agreement with Jefferies entered on August 4, 2020, and amended and restated on August 2, 2024, 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. As of September 30, 2024, we have not sold any shares of common stock under such Open Market Sale Agreement. We had a shelf registration statement (the Prior Registration Statement) filed with the SEC that expired on August 3, 2024. The Prior Registration Statement included a base prospectus registering the offering, issuance, and sale by us of up to $250.0 million in the aggregate of the securities identified from time to time in one or more offerings, including the $100.0 million of shares of our common stock that may be offered, issued and sold under the Open Market Sale Agreement. On August 2, 2024, we filed a new shelf registration statement (the New Registration

Statement) with the SEC to replace the Prior Registration Statement. The New Registration Statement was declared effective on August 9, 2024 by the SEC. The New Registration Statement includes a base prospectus to register the offering, issuance and sale by us of up to $250.0 million in the aggregate of securities identified from time to time in one or more offerings, including up to $100.0 million of shares of our common stock that may be offered, issued and sold under the Open Market Sale Agreement.

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.

The biopharmaceutical industry is subject to extensive regulatory obligations and policies that are subject to change, including due to judicial challenges.*

On June 28, 2024, the US Supreme Court issued an opinion holding that courts reviewing agency action pursuant to the Administrative Procedure Act “must exercise their independent judgment” and “may not defer to an agency interpretation of the law simply because a statute is ambiguous.” The decision will have a significant impact on how lower courts evaluate challenges to agency interpretations of law, including those by the FDA and other agencies with significant oversight of the biopharmaceutical industry. The new framework is likely to increase both the frequency of such challenges and their odds of success by eliminating one way in which the government previously prevailed in such cases. As a result, significant regulatory policies will be subject to increased litigation judicial scrutiny. Any resulting changes in regulation may result in unexpected delays, increased costs, or other negative impacts on our business that are difficult to predict.

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 our products 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 US 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 our products, or any product candidates for which we obtain regulatory approval in the future. In particular, in March 2010, 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 US pharmaceutical industry. On June 17, 2021, the US Supreme Court dismissed the legal challenge to the Affordable Care Act brought by several states (which argued that, without the individual mandate, the entire Affordable Care Act was unconstitutional) without specifically ruling on the constitutionality of the law. It is unclear how future actions before the Supreme Court, other such litigation, and the healthcare reform measures of future presidential administrations 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 the costs of healthcare and/or impose price controls may adversely affect, for example:

- the demand for our products, 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.

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 US, 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 US, there have been several 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.

On March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which, among other changes, eliminated the statutory Medicaid drug rebate cap, which was previously set at 100% of a drug's average manufacture price, for single source and innovator multiple source drugs, as of January 1, 2024. The American Rescue Plan Act also temporarily increased premium tax credit assistance for individuals eligible for subsidies under the Affordable Care Act for 2021 and 2022 and removed the 400% federal poverty level limit that otherwise applies for purposes of eligibility to receive premium tax credits. The Inflation Reduction Act (IRA) extended this increased tax credit assistance and removal of the 400% federal poverty limit through 2025. Additionally, beginning in April 2013, the Budget Control Act of 2011 created an automatic reduction of Medicare payments to providers of up to 2%. As a result of the COVID-19 pandemic, this reduction was temporarily suspended from May 1, 2020 through March 31, 2022, with subsequent reductions to 1% from April 1, 2022 through June 30, 2022. The 2% reduction was then reinstated and has been in effect since July 1, 2022, and will remain in effect through the first eight months in which the fiscal year 2032 sequestration order is in effect, unless additional Congressional action is taken. Moreover, on June 16, 2022, the Federal Trade Commission issued a policy statement stating its intent to increase enforcement scrutiny of "exclusionary rebates" to PBMs and other intermediaries that "foreclose competition." On August 16, 2022, President Biden signed into law the IRA, which, among other reforms, allows Medicare to: beginning in 2026, establish a "maximum fair price" for a fixed number of pharmaceutical and biological products covered under Medicare Parts B and D following a price negotiation with CMS; beginning in 2023, penalize drug companies that raise prices for products covered under Medicare Parts B and D faster than inflation; and beginning in 2025, impose new discount obligations on pharmaceutical and biological manufacturers for products covered under Medicare Part D. CMS continues to take steps to implement the IRA. For example, on August 29, 2023, CMS released the initial list of ten drugs covered under Medicare Part D subject to price negotiations, and on August 15, 2024, CMS released the negotiated maximum prices for such drugs that will be effective beginning in 2026. None of our products were listed among the first ten products slated for the program as announced on August 29, 2023. Additionally, on June 26, 2024, CMS released a list of 64 Medicare Part B products that will have an adjusted coinsurance rate based on the inflationary rebate provisions of the IRA for the time period of July 1, 2024 to September 30, 2024. Most recently, on October 2, 2024, CMS released final guidance outlining the process for the second round of price negotiations for products subject to the "maximum fair price" provision. While it remains to be seen how the drug pricing provisions imposed by the IRA will affect the broader pharmaceutical industry, several pharmaceutical manufacturers and other industry stakeholders have challenged the law, including through lawsuits brought against the DHHS, the Secretary of the DHHS, CMS, and the CMS Administrator challenging the constitutionality and administrative implementation of the IRA's drug price negotiation provisions

The Biden administration has also taken executive action to address drug pricing and other healthcare policy changes. For example, on September 12, 2022, President Biden issued an Executive Order to promote biotechnology and biomanufacturing innovation that included several methods through which the Biden Administration would support the advancement of biotechnology and biomanufacturing in healthcare. On October 14, 2022, President Biden issued an Executive Order on Lowering Prescription Drug Costs for Americans which instructed the Secretary of the DHHS to consider whether to select for testing by the CMS Innovation Center new health care payment and delivery models that would lower drug costs and promote access to innovative drug therapies for beneficiaries enrolled in the Medicare and Medicaid programs. On February 14, 2023, the DHHS issued a report in response to the October 14, 2022, Executive Order, which, among other things, selects three potential drug affordability and accessibility models to be tested by the

CMS Innovation Center. Specifically, the report addresses: (1) a model that would allow Part D Sponsors to establish a "high-value drug list" setting the maximum out-of-pocket costs for certain common generic drugs at $2 per month per drug; (2) a Medicaid-focused model that would establish a partnership between CMS, manufacturers, and state Medicaid agencies that would result in multi-state outcomes-based agreements for certain cell and gene therapy drugs; and (3) a model that would adjust Medicare Part B payment amounts for Accelerated Approval Program drugs to advance the developments of novel treatments. Additionally, consistent with President Biden's previous announcements in connection with the Cancer Moonshot initiative, on June 27, 2023, the Center for Medicare Innovation at CMS announced a new model, the Enhancing Oncology Model, that is designed to make high-quality cancer care more affordable to both patients and Medicare.

Other proposed administrative actions may affect our government pricing responsibilities. For example, there are pending legal and legislative developments relating to the 340B Drug Pricing Program, including ongoing litigation challenging federal enforcement actions against manufacturers and recently introduced and enacted state legislation. It remains to be seen how these drug pricing initiatives will affect the broader pharmaceutical industry.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing. Specifically, several US states and localities have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports, and/or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Other state laws prohibit certain marketing-related activities, including the provision of gifts, meals or other items to certain healthcare providers, and restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs. Several state laws require disclosures related to state agencies and/or commercial purchasers with respect to price increases and new product launches that exceed certain thresholds as identified in the relevant statutes. Another emerging trend at the state level is the establishment of prescription drug affordability boards, some of which will prospectively permit certain states to establish upper payment limits for drugs that the state has determined to be "high-cost." Some of these laws and regulations contain ambiguous requirements that government officials have not yet clarified. Given the lack of clarity in the laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent federal and state laws and regulations.

Furthermore, the increased emphasis on managed healthcare in the US and on country and regional pricing and reimbursement controls in the EU and the UK 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, 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.

We cannot predict the likelihood, nature, or extent of health reform initiatives that may arise from future legislation or administrative action. 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 "Business – Government Regulation – Healthcare Reform" contained in Part I, Item 1 of our Annual Report on Form 10-K for the year ended December 31, 2023, for additional information.

Regulatory approval for any approved product is limited by the FDA, the EC 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 our products 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 EC 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 and for REZLIDHIA is only approved for use in adult patients with R/R AML with a susceptible IDH1 mutation as detected by an FDA-approved test. Further, GAVRETO is approved by the FDA for the treatment of adult patients with metastatic RET fusion-positive NSCLC and has a conditional approval for the treatment of adult and pediatric patients 12 years of age and older with advanced or metastatic RET fusion-positive thyroid cancer. 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, or if we are not able to maintain a conditional approval or transition a conditional approval to full approval, 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 our products 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 us. Regulatory authorities in the US 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 a global pandemic, global tensions arising from the Russian-Ukrainian war and Hamas-Israel war 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. 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 potential future impacts of a global pandemic, the global tensions arising from the Russian-Ukrainian war and Hamas-Israel war 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 effects of the COVID-19 pandemic, for several of our development programs, we experienced disruption or delay in our ability to enroll and assess patients, maintain patient enrollment, supply study drugs, report trial results, or interact with regulators, ethics committees or other important agencies due to limitations in employee resources or otherwise. In addition, in the event that a global pandemic occurs in the future, some patients in our clinical trial 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 may be adversely affected if a global pandemic continues and persists for an extended period of time, and we may experience significant disruptions to our clinical development timelines, which would adversely affect our business, financial condition, results of operations and growth prospects in the future.

We have conducted in the past and are currently conducting or may conduct in the future clinical trials in the US and outside the US including Ukraine, Russia and Israel. Recent actions taken by the Russian Federation in Ukraine and surrounding areas have destabilized the region and caused the adoption of comprehensive sanctions by, among others, the EU, the US and the UK, which restrict a wide range of trade and financial dealings with Russia and Russian persons, as well as certain regions in Ukraine. Also, the recent global tensions arising from the Hamas-Israel war may result in disruptions in the broader global economic environment. Further, some patients may not be able to comply with clinical trial protocols if the conflict impedes patient movement or interrupts healthcare services. In addition, clinical trial site initiation and patient enrollment may be delayed, and we may not be able to access sites for initiation and monitoring in regions affected by the Russian-Ukrainian war or the Hamas-Israel war including due to the prioritization of hospital resources away from clinical trials or as a result of warfare, violence, government-imposed curfews, or events or other governmental actions that restrict movement. We could also experience disruptions in our supply chain or limits our ability to obtain sufficient materials for our drug products in certain regions.

Public perception of the risk-benefit balance for our product candidates may be affected by adverse events in clinical trials involving our product candidate or other 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, 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, 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 US, 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 rely on and intend to continue relying 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 our products or any product candidates for clinical trials. We currently use one active pharmaceutical ingredient manufacturer and one finished goods manufacturer for each of our products. 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 active pharmaceutical ingredients 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 US, as our limited source of the materials they supply or the finished products they manufacture. In the ordinary course of business, we enter into agreements with contract manufacturers to manufacture our inventory products. For example, in October 2024, we entered into an agreement with a third-party contract manufacturer to manufacture TAVALISSE that are expected to be delivered starting in fiscal year 2026 through 2029, for a total contract price of approximately $24.0 million. Although the agreement provides a cancellation clause with or without cause upon written notice, we may or may not be subject to payment of a cancellation fee. The level of cancellation fee is generally dependent on the timing of the written notice in relation to the commencement date of work, with the maximum cancellation fee equal to the full price of the work order. 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. Our third-party manufacturers import certain materials from China to produce our products. The tensions between the US and China have led to a series of tariffs and sanctions being imposed by the US on imports from China mainland, as well as other business restrictions. Such tensions could adversely impact us and our third-party manufacturers. 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 investigational new drug (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 EMA, 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 a global 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 us, 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, MHRA 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 may 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.

We commercialize our products in the US and we have entered into commercialization agreements with third parties to commercialize fostamatinib outside the US. 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, 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 our products or any of our product candidates, when and if approved, whether due to the impacts of a global 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 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. The 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.

If we are unable to obtain regulatory approval to market products in the US 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 US, 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 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 US, 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 have orphan drug designations from the FDA but we may not be able to obtain additional orphan drug designations in the future, or maintain the orphan drug designations or exclusivity for the approved drugs for the treatment of respective indications, or we may be unable to maintain the benefits associated with orphan drug designations, including the potential for market exclusivity.

We have an orphan drug designation in the US for fostamatinib for the treatment of ITP and wAIHA, and for olutasidenib for the treatment of AML. Also, pralsetinib has an orphan drug designation in the US for the treatment of adult patients with metastatic RET fusion-positive NSCLC, for the treatment of advanced or metastatic RET fusion-positive thyroid cancer, and for the treatment of advanced or metastatic RET-mutant medullary thyroid carcinoma. 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 US, or a patient population greater than 200,000 in the US where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the US. In the US, 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 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 US, 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 in the US, we may not be the first to obtain marketing approval for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products or we might not maintain our orphan drug designation. In addition, exclusive marketing rights in the US 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.

In addition, Congress is considering updates to the orphan drug provisions of the FDCA in response to a recent 11th Circuit decision. Any changes to the orphan drug provisions could change our opportunities for, or likelihood of success in obtaining, orphan drug exclusivity and would materially adversely affect our business, financial condition, results of operations, cash flows and prospects.

Risks Related to Commercialization

Our prospects are highly dependent on our commercial products. To the extent that the commercial success of our products in the US 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.*

We are focusing a significant portion of our activities and resources on our products, 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 our products in the US. We have also entered into exclusive commercialization agreements with third parties to commercialize fostamatinib outside the US, and we plan to further enter partnership with existing or other third parties to commercialize our products outside the US in the future.

Sustained successful commercialization of our products is subject to many risks and uncertainties, including the impact of a global pandemic on the successful commercialization in the US, as well as the successful commercialization efforts for our products through our collaborative partners. 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.

There are many factors that could cause the commercialization of our products to be unsuccessful, including a number of factors that are outside our control. The commercial success of our products depends on the extent to which patients and physicians accept and adopt our products to treat the related diseases. We also do not know how physicians, patients and payors will respond to our future price increases of our products. Physicians may not prescribe our products and patients may be unwilling to use our products if coverage is not provided or reimbursement is inadequate to cover a significant portion of the cost. Our products compete, 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 our products in clinical development in additional indications may adversely impact the commercialization and potential of fostamatinib. Thus, significant uncertainty remains regarding the commercial potential of our products.

Market acceptance of our products 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;
- potential future impacts, if any, due to the effects of a global pandemic and the global tensions arising from the Russian-Ukrainian war and Hamas-Israel war;
- 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;
- a positive HTA concluding that the product is cost-effective and the HTA bodies issuing a positive recommendation for the use of the product as a first or second line of treatment for the granted therapeutic indication;
- 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 our products, 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 2021, we experienced lower than anticipated sales of our products due to continuing impacts of physician and patient access issues created by the COVID-19 pandemic. From time to time, our net product sales are 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 development and commercialization of fostamatinib in Kissei, Grifols, Medison and Knight's territories, and of olutasidenib in Kissei territory. As a consequence of our license agreements with our collaboration partners, 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 US. 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 COVID-19 pandemic has resulted in increased travel restrictions and extended shutdowns of certain businesses in the US 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 our products 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 may 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 payors to contain or reduce their costs, including by taking the following steps, among others: decreasing the portion of costs payors will cover, ceasing to provide full payment for certain products depending on outcomes, and/or not covering certain products at all. If payors 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 our products or any of our product candidates in some jurisdictions. Even if coverage is provided, the approved reimbursement amount may not be at a rate that covers our costs, including research, development, manufacture, sale and distribution. In the US, 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 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 payors 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.

On January 1, 2025, the new HTA Regulation, Regulation No 2021/2282 on Health Technology Assessment (HTA Regulation) will start applying to new cancer medicines and advanced therapy medicinal products, and will impose a new procedure for the assessment of the pricing and reimbursement of medicinal products. The HTA Regulation intends to foster cooperation among EU member states in assessing health technologies and provide a procedure for joint clinical assessments of medicinal products at a centralized level. It requires companies applying for products in scope to make relevant submissions for the joint clinical assessment, in line with a number of prespecified criteria. By 2030 it will apply to all medicinal products.

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 effects of a global pandemic, depending on its scale and duration, may 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 our products 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 our products and retain experienced commercial personnel, our business will be substantially harmed.

We continuously expend significant time and resources to maintain a sales force that is credible and compliant with applicable laws in marketing our products. In addition, we must continually train our sales force to ensure that an appropriate and compliant message about our products 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 our products, our efforts to successfully commercialize our products 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 our products. As a result, we will be required to expend significant time and resources to market, sell, and distribute our products to hematologists and hematologist-oncologists. There is no guarantee that the marketing strategies we have developed, 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 our products. 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.

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, we may be unable to realize the commercial potential of our products. Also, to the extent that the commercial opportunities for our products 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 our products, which could have an adverse impact on our business, financial condition and results of operations.

We may 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 our products 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 US and by comparable authorities in other countries. The process of obtaining regulatory approvals in the US 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 our products for any individual, additional indications. For example, in June 2022, we announced that the top-line results from our Phase 3 trial in wAIHA did not demonstrate statistical significance in the primary efficacy endpoint of durable hemoglobin response in the overall study population. While we conducted an in-depth analysis of these data to better understand differences in patient characteristics and outcomes and submitted these findings to the FDA, in October 2022, we announced that we received guidance from the FDA of these findings. Based on the result of the trial and the guidance from the FDA, we did not file an sNDA for wAIHA.

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 public health emergencies including a global pandemic, 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 our products 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 force majeure events;
- 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.

Further, evolving FDA standards may cause additional setbacks. In 2023, FDA published guidance documents and a final rule which all concern clinical trial requirements. In June 2023, FDA published a draft guidance, E6(R3) Good Clinical Practice, which seeks to unify standards for clinical trial data for the International Council for Harmonisation of Technical Requirements of Pharmaceuticals for Human Use member countries and regions. In August 2023, FDA published a guidance document, Informed Consent, Guidance for IRBs, Clinical Investigators, and Sponsors, which supersedes past guidance and finalizes draft guidance on informed consent. Further, in December 2023, FDA published a final rule, Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations, which allows exceptions from informed consent requirements when a clinical investigation poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of human subjects.

Alterations to clinical trial requirements, including due to judicial challenges, may affect recruitment and retention of patients and may hinder or delay a clinical trial. Further, changes to data requirements may cause FDA or comparable foreign regulatory authorities to disagree with data from preclinical studies or clinical trials, and may require further studies. Changes to trial requirements or trial data may increase costs and delay product development.

General Risk Factors

Global economic conditions could adversely impact our business.

Deterioration in the macroeconomic economy could lead to losses or defaults by our customers or suppliers, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition. The global financial markets and economy are currently, and have from time to time experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, rising interest and inflation rates, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability.

Any significant deterioration in the US economy would likely affect the operation of our business and ability to raise capital. In addition, US debt ceiling and budget deficit concerns have increased the possibility of additional credit-rating downgrades and economic slowdowns, or a recession in the US. Although US lawmakers passed legislation to raise the federal debt ceiling on multiple occasions, ratings agencies have lowered or threatened to lower the long-term sovereign credit rating on the US. The impact of this or any further downgrades to the US government's sovereign credit rating or its perceived creditworthiness could adversely affect the US and global financial markets and economic conditions.

The global financial markets and economy may also be adversely affected by the current or anticipated impact of military conflict, including the ongoing Russian-Ukrainian war, and the Hamas-Israel war, terrorism or other geopolitical events. Sanctions imposed by the US and other countries in response to such conflicts, including the Russian-Ukrainian war and the Hamas-Israel war, may also adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability.

The US 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 US 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 US goods. It remains unclear what the US 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 US or global economy or certain sectors thereof and, thus, could adversely impact our businesses.

Bank failures or other events affecting financial institutions could adversely impact our liquidity and other business.

Financial institutions have recently experienced, and may experience in the future, industry instability and failures which have led to disruptions in access to bank deposits or lending commitments. In 2023, the closures of Silicon Valley Bank (SVB) and Signature Bank and their placement into receivership with the Federal Deposit Insurance Corporation (FDIC), as well as the FDIC's seizure and sale of First Republic Bank, created bank-specific and broader financial institution liquidity risk and concerns. On March 12, 2023, federal regulators announced that the FDIC would complete its resolution of SVB in a manner that fully protects all depositors. On March 27, 2023, First Citizens Bank (FCB) announced that it has entered into an agreement with FDIC to purchase all of the asset and liabilities of SVB. Customers of SVB automatically become customers of FCB following the acquisition.

We maintain a depository relationship with SVB/FCB and other banking institutions. All of our cash deposits are accessible to us, and we do not anticipate any losses with respect to such funds. Since the March 2023 financial institution failure, there has been a heightened risk and greater focus on the potential failures of other banks in the future. If these banks fail in the future, we may not be able to immediately (or ever) recover our cash in excess of the FDIC insured limits which would adversely impact our operating liquidity and could negatively impact our operations, results of operations and financial performance. Although we believe our exposure is limited, if in the future any of the financial institutions that we maintain depository or lending relationships were to be placed into receivership, we may be unable to access such funds to meet our working capital requirements. In addition, if any of our customers, suppliers or other parties with whom we conduct business are unable to access funds, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected. Although

we assess our banking and customer relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impacted by factors that affect us, the financial institutions with which we have credit agreement or arrangements directly, or the financial services industry or economy in general.

Shareholder activism and private securities-related litigation could cause material disruption to our business.

Publicly traded companies have increasingly become subject to campaigns by our stakeholders, including investors, and more recently regulatory organizations advocating corporate actions such as actions related to Environmental Social Governance (ESG) matters, impacts of climate change, financial restructuring, increased borrowing, dividends, share repurchases and 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.

There is a growing emphasis from select investors, regulators, and other stakeholders on corporate responsibility, particularly regarding ESG factors. Some investors and advocacy groups utilize these factors to shape investment strategies, potentially opting out of investing in our company if they perceive our corporate responsibility policies as insufficient. Third-party providers offering corporate responsibility ratings and reports have surged to meet rising investor demand, with numerous organizations evaluating companies on ESG matters, and these evaluations receive widespread attention. A low ESG or sustainability rating from such providers could lead certain investors to overlook our common stock in favor of competitors. Institutional investors, in particular, use these ratings to compare companies, and any perceived lag in our ESG efforts might prompt voting decisions or other actions to hold our board accountable. Furthermore, evolving assessment criteria for corporate responsibility practices may raise expectations, compelling us to undertake costly initiatives to meet new standards. Failure to meet these evolving criteria could reinforce the perception of inadequate corporate responsibility policies. Non-compliance could also lead to reputational damage if our procedures or standards fall short of stakeholder expectations.

Securities-related class action lawsuits and/or derivative lawsuits have often been brought against companies, including biotechnology and biopharmaceutical companies, that experience volatility in the market price of their securities. It is possible that such lawsuit will be filed, or allegations from stockholders with this matter. Such lawsuits and any other related lawsuits are subject to inherent uncertainties, and the actual defense and disposition costs will depend upon many unknown factors. The outcome of such lawsuits is necessarily uncertain. We could be forced to expend significant resources in the defense of the pending lawsuits and any additional lawsuits, and we may not prevail.

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 our 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 (DGCL), which imposes certain restrictions relating to transactions with major stockholders, may discourage, delay or prevent a third party from acquiring us.

Our bylaws designate a state or federal court located within the State of Delaware as the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our current or former directors, officers, stockholders, or other employees.

Our bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of us under Delaware law, (ii) any action asserting a claim of breach of a fiduciary duty by any current or former director, officer, or other employee of ours that is owed to us or our stockholders, (iii) any action asserting a claim against us or any of our directors, officers, or other employees arising pursuant to any provision of the DGCL or our Amended and Restated Certificate of Incorporation and our bylaws (as either may be amended from time to time), (iv) any action asserting a claim against us governed by the internal affairs doctrine, or (v) any other action asserting an "internal corporate claim," as defined under Section 115 of the DGCL. The forgoing provisions do not apply to any claims arising under the Securities Act and, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States will be the sole and exclusive forum for resolving any action asserting a claim arising under the Securities Act.

These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our current or former directors, officers, or other employees, which may discourage lawsuits with respect to such claims. There is uncertainty as to whether a court would enforce such provisions, and the enforceability of similar choice of forum provisions in other companies' charter documents has been challenged in legal proceedings. It is possible that a court could find these types of provisions to be inapplicable or unenforceable, and if a court were to find the choice of forum provision to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations, and financial condition.

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, regulations and national and EU codes of conduct, 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 future success depends on our ability to attract and retain key employees and relationships.

We are highly dependent on the commercial, research and development, clinical, business development, financial and legal expertise of our executive officers, as well as the other principal members of our management. We expect to continue hiring and retaining qualified personnel which is critical to our success. Replacing key employees and executive officers may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize drugs. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar 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.

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

Securities Trading Plans of Directors and Executive Officers

During the three months ended September 30, 2024, none of our directors or executive officers adopted or terminated any contract , instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any “non-Rule 10b5-1 trading arrangement” as defined in Item 408 of Regulation S-K under the Securities Exchange Act of 1934, as amended.

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
1.1	Amended and Restated Open Market Sale Agreement SM, dated August 2, 2024, by and between Rigel Pharmaceuticals, Inc. and Jefferies LLC (filed as an exhibit to Rigel's Registration Statement on Form S-3, dated August 2, 2024 and incorporated herein by reference).
3.1	Amended and Restated Certificate of Incorporation (filed as an exhibit to Rigel's Current Report on Form 8-K, dated June 24, 2003 and incorporated herein by reference).
3.2	Amended and Restated Bylaws (filed as an exhibit to Rigel's Current Report on Form 8-K, dated November 3, 2022 and incorporated herein by reference).
3.3	Certificate of Amendment to the Amended and Restated Certificate of Incorporation (filed as an exhibit to Rigel's Current Report on Form 8-K, dated May 29, 2012 and incorporated herein by reference).
3.4	Certificate of Amendment to the Amended and Restated Certificate of Incorporation (filed as an exhibit to Rigel's Current Report on Form 8-K, dated May 18, 2018 and incorporated herein by reference).
3.5	Certificate of Amendment to the Amended and Restated Certificate of Incorporation (filed as an exhibit to Rigel's Current Report on Form 8-K, dated June 27, 2024 and incorporated herein by reference).
4.1	Form of warrant to purchase shares of common stock (filed as an exhibit to Rigel's Registration Statement on Form S-1, filed on September 15, 2000, as amended and incorporated herein by reference).
4.2	Specimen Common Stock Certificate (filed as an exhibit to Rigel's Current Report on Form 8-K dated June 24, 2003 and incorporated herein by reference).
10.1#^	Collaboration and License Agreement with Kissei Pharmaceutical Co., Ltd., dated September 3, 2024 .
10.2#^	Supply Agreement with Kissei Pharmaceutical Co., Ltd., dated September 3, 2024 .
10.3# ^	Amendments to Collaboration and License Agreement with Kissei Pharmaceutical Co., Ltd., dated October 29, 2018.
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.

+ Indicates a management contract or compensatory plan or arrangement.

^ Certain marked information has been omitted from this exhibit because it is both not material and is the type that the registrant treats as private and confidential.

** 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.*

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 7, 2024

By: /s/ DEAN L. SCHORNO
Dean L. Schorno
Chief Financial Officer
(Principal Financial Officer)
Date: November 7, 2024

Exhibit 10.1

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [**], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

COLLABORATION AND LICENSE AGREEMENT

by and between

RIGEL PHARMACEUTICALS, INC.,

and

KISSEI PHARMACEUTICAL CO., LTD.

September 3, 2024

COLLABORATION AND LICENSE AGREEMENT

This Collaboration and License Agreement (this " **Agreement**") is entered into as of September 3, 2024 (the "**Effective Date**"), by and between **Rigel Pharmaceuticals, Inc.**, a Delaware company having an address at 611 Gateway Boulevard, Suite 900, South San Francisco, CA 94080, USA ("**Rigel**") and **Kissei Pharmaceutical Co. Ltd.**, a Japanese company having an address at 19-48 Yoshino, Matsumoto, Nagano 399-8710, Japan (" **Kissei**"). Rigel and Kissei may be referred to herein individually as a "**Party**" or collectively as the " **Parties**".

RECITALS

WHEREAS, Rigel is a biopharmaceutical company that conducts research, development, manufacturing and commercialization of pharmaceutical products in the U.S.;

WHEREAS, Rigel has entered into a worldwide exclusive license with respect to Olutasidenib (also known as REZLIDHIA® in the U.S.) under that certain License and Transition Services Agreement between Rigel and Forma Therapeutics, Inc. (now Novo Nordisk) dated July 27, 2022 ("**Rigel-Forma Agreement**");

WHEREAS, Olutasidenib has been approved by the FDA for the treatment of adult patients with relapsed or refractory acute myeloid leukemia with a susceptible isocitrate dehydrogenase-1 mutation as detected by an FDA-approved test;

WHEREAS, Kissei is a pharmaceutical company possessing substantial resources and expertise in the development and commercialization of pharmaceutical products; and

WHEREAS, Kissei desires to obtain, and Rigel is willing to grant, an exclusive sublicense under the Rigel-Forma License Agreement to Develop and Commercialize the Product in the Field in Japan, Republic of Korea and Taiwan (defined as the "**Kissei Territory**" below), subject to the terms and conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Agreement, the Parties hereby agree as follows:

1. DEFINITIONS

Unless specifically set forth to the contrary herein, the following terms, whether used in the singular or plural, shall have the respective meanings set forth below:

1.1 "**Active Ingredient**" means a component in a pharmaceutical product that provides pharmacological activity in the mitigation or treatment of a disease or condition. Formulation components of a pharmaceutical product, such as coatings, stabilizers, excipients or solvents, adjuvants, controlled release technologies, and drug delivery vehicles, shall not be deemed to be Active Ingredients.

1.2 "**Additional Commercial Milestone Payments**" has the meaning set forth in Section 8.5.2.

1.3 "**Additional Development Milestone Payments**" has the meaning set forth in Section 8.5.1.

1.4 "**Affiliate**" means, with respect to any Person, any other Person that, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with such Person, but for only so long as such control exists. As used in this definition, " control" means: (a) to possess, directly or indirectly, the power to direct the management or policies of an entity, whether through ownership of voting securities, by contract relating to voting rights or corporate governance; or (b) direct or indirect beneficial ownership of more than fifty percent (50%) (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of the voting share capital or other equity interest in such entity.

1.5 "**Agreement**" has the meaning set forth in the Preamble.

1.6 "**AML**" means acute myeloid leukemia.

1.7 "**ANS**" has the meaning set forth in Section 8.4.2(a).

1.8 "**Applicable Laws**" means the applicable provisions of any and all national, supranational, regional, state and local laws, treaties, statutes, rules, regulations, administrative codes, guidance, ordinances, judgments,

decrees, directives, injunctions, orders, permits (including MAAs) of or from any court, Regulatory Authority or governmental agency or authority having jurisdiction over or related to the subject item.

1.9 "**Anti-Corruption Laws**" means any law or regulation in a U.S. or any non U.S. jurisdiction regarding bribery or any other corrupt activity, including the U.S. Foreign Corrupt Practices Act of 1977, as amended, and the U.K. Bribery Act 2010, as amended.

1.10 "**Approved NDA**" means any FDA-approved NDA for the Product in the Initial Indication in the U.S.

1.11 "**Auditor**" has the meaning set forth in Section 8.8.

1.12 "**Base Percent**" has the meaning set forth in Section 8.4.1(b).

1.13 "**Business Day**" means a day on which banking institutions in San Francisco, California and in Tokyo, Japan are open for business, excluding any Saturday or Sunday.

1.14 "**Calendar Quarter**" means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31 of each calendar year, provided that: (a) the first Calendar Quarter of the Term shall begin on the Effective Date and end on the first to occur of March 31, June 30, September 30 or December 31 thereafter and the last Calendar Quarter of the Term shall end on the last day of the Term; and (b) the first Calendar Quarter of a Commercialization Term for a Product shall begin on the First Commercial Sale of such Product in such country and end on the first to occur of March 31, June 30, September 30 or December 31 thereafter and the last Calendar Quarter of a Commercialization Term for a Product shall end on the last day of such Commercialization Term.

1.15 "**Calendar Year**" means each successive period of twelve (12) months commencing on January 1 and ending on December 31, provided that: (a) the first Calendar Year of the Term shall begin on the Effective Date and end on the first December 31 thereafter and the last Calendar Year of the Term shall end on the last day of the Term; and (b) the first Calendar Year of a Commercialization Term for a Product shall begin on the First Commercial Sale of such Product in such country and end on the first December 31 thereafter and the last Calendar Year of a Commercialization Term for a Product shall end on the last day of such Commercialization Term.

1.16 "**CDx Company**" has the meaning set forth in Section 4.1.3.

1.17 "**CDx Company Agreement**" has the meaning set forth in Section 4.1.3.

1.18 "**Claim**" has the meaning set forth in Section 11.3.

1.19 "**Complementary Product**" means any proprietary (i.e., not generic) product or compound, other than Olutasidenib or the Product, that is **.

1.20 "**Compound Invention**" has the meaning set forth in Section 9.1.2(b).

1.21 "**Clinical Study**" or "**Clinical Studies**" means any human clinical study of a Product.

1.22 "**CMC**" means chemistry, manufacturing and controls.

1.23 "**CMC Data**" means any data included in the "Chemistry, Manufacturing and Controls" portion of a Regulatory Filing or in any supporting development reports thereto, in each case, with respect to any Product in any country in the world.

1.24 "**Combination Product**" means a product that includes a Product and at least one (1) additional Active Ingredient other than Olutasidenib that is either co-formulated or co-packaged with the Product and sold together for a single price.

1.25 "**Commercial Activities Country**" has the meaning set forth in Section 8.5.2.

1.26 "**Commercial Activities Notice**" has the meaning set forth in Section 8.5.2.

1.27 "**Commercial Milestone Negotiation Period**" has the meaning set forth in Section 8.5.2.

1.28 "**Commercialization Plan**" has the meaning set forth in Section 6.2.

1.29 "**Commercialization Term**" means, on a Product-by-Product and country-by-country basis, the period commencing on the First Commercial Sale of such Product in such country and ending on the latest of (a) the expiration of the last-to-expire Valid Claim of the Rigel Patents and Joint Patents covering such Product in such country, including its composition, method of manufacture, or method of use, (b) the expiration of Regulatory Exclusivity for such Product in such country, and (c) ten (10) years after the First Commercial Sale of such Product in such country.

1.30 "**Commercialization**" or "**Commercialize**" means the marketing, promotion, sale (and offer for sale or contract to sell), distribution, importation or other commercial exploitation (including Pricing and Reimbursement Approvals activities) for a Product in the Kissei Territory. For clarity, Commercialization does not include Manufacturing.

1.31 "**Commercially Reasonable Efforts**" means, with respect to a Party's obligations that relate to the achievement of an objective related to a Product, at any given time as the case may be, those diligent good faith efforts, expertise and resources used by a similarly situated entity in the pharmaceutical industry having similar resources and expertise as such Party, for such similar entity's own products ** of a similar modality with similar commercial potential at a similar stage in their lifecycle **, taking into consideration the proprietary position, strength and duration of patent protection and anticipated market exclusivity, competitive market conditions, profitability, and financial return **, issues of safety and efficacy, product profile, difficulty in developing or manufacturing, the regulatory requirements involved; and all other relevant legal, scientific, technical, operational and commercial factors.

1.32 "**Companion Diagnostic**" means a companion diagnostic test that detects the presence of a mutation in IDH1.

1.33 "**Companion Diagnostic Right of Reference**" is defined in Section 5.3.1.

1.34 "**Competing Product**" means any compound or product, other than Olutasidenib or the Product, that **.

1.35 "**Competing Program**" has the meaning set forth in Section 2.9.1.

1.36 "**Confidential Information**" means any and all confidential or proprietary information and data, including Rigel Technology and Joint Technology, and all other scientific, pre-clinical, clinical, regulatory, manufacturing, marketing, financial and commercial information or data, whether communicated in writing or orally or by any other method, which is provided by one Party to the other Party in connection with this Agreement. Rigel Technology and Rigel Data and Compound Inventions are the Confidential Information of Rigel. Joint Technology and the terms of this Agreement are the Confidential Information of both Parties.

1.37 "**Control**", "**Controls**" or "**Controlled by**" means, with respect to any intellectual property right (including any Patent or Know-How), the possession of (whether by ownership or license, other than pursuant to this Agreement) the ability of a Person or its Affiliates to assign, transfer, or grant access to, or to grant a license or sublicense of, such right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party existing at the time such Person would be required hereunder to assign, transfer or grant another Person such access or license or sublicense. Notwithstanding the foregoing, with respect to any Patent, Know-How, Regulatory Approvals or other intellectual property right (a) acquired or in-licensed by Rigel for which Rigel would be required to make payments to any Third Party in connection with the license or access granted to Kissei under this Agreement ("**Rigel Third Party In-License**"), such intellectual property shall be treated as "Controlled" by Rigel to the extent that, and only to the extent that and for so long as, Kissei agrees and does promptly pay to Rigel all such applicable payments to Rigel arising out of the grant and exercise of the license to Kissei hereunder as further described in Section 2.1.4, or (b) of an acquirer of a Party, such Patent, Know-How, Regulatory Approvals or other intellectual property shall not be "Controlled" by such Party.

1.38 "**Cost of Goods**" means, with respect to the Product, the fully burdened cost to manufacture and supply such Product, which means: (a) in the case of **; and (b) in the case of **.

1.39 "**Cover**", "**Covers**" or "**Covered**" means, as to a compound or product and a Patent, that, in the absence of a license granted under, or ownership of, such Patent, the using, selling, offering for sale or importation of such compound or product would infringe any claim of such Patent.

1.40 "**CTN**" means the Clinical Study Notification filed with the PMDA which is required to commence human clinical trials of a pharmaceutically active agent in humans in Japan.

1.41 "**Data**" means any and all scientific, technical, test, marketing, or sales data pertaining to any Product that is generated by or on behalf of Rigel, Kissei, and their respective Affiliates and sublicensees, including research data, clinical pharmacology data, pre-clinical data, clinical data, clinical study reports, or submissions made in association with an IND, CTN, or MAA with respect to any Product.

1.42 "**Development,**" "**Developing**" or "**Develop**" means, with respect to Products, the pre-clinical and clinical development activities conducted before or after obtaining Regulatory Approval that are reasonably related to or leading to the development, preparation and submission of data and information to a Regulatory Authority for the purpose of obtaining, supporting, maintaining, or expanding a Regulatory Approval, including but not limited to all activities related to pharmacokinetic profiling, design and conduct of pre-clinical development, non-clinical development, pre-clinical studies, in vitro studies, CMC, Clinical Studies, other studies and scientific activities ordinarily conducted in the pharmaceutical industry in the Kissei Territory or the Rigel Territory, as applicable and as a prerequisite to or in connection with a Clinical Study, regulatory affairs, statistical analysis, report writing and Regulatory Filing creation and submission, including (a) fulfilling Post-Approval Commitments and (b) conducting studies that will result in an amendment or supplement to the NDA, including the indication(s) included in the product labelling for the Product.

1.43 "**Development Costs**" means the costs incurred by a Party or for its account or by the Parties jointly, during the Term and pursuant to this Agreement, that are specifically directed (or reasonably allocable) to the Development of a Product. The Development Costs shall include ** and **.

1.44 "**Development Activities Country**" has the meaning set forth in Section 8.5.1.

1.45 "**Development Activities Notice**" has the meaning set forth in Section 8.5.1.

1.46 "**Development Milestone Negotiation Period**" has the meaning set forth in Section 8.5.1.

1.47 "**Development Plan**" has the meaning set forth in Section 4.3.

1.48 "**Effective Date**" has the meaning set forth in the Preamble.

1.49 "**ENS**" has the meaning set forth in Section 8.4.2.

1.50 "**Executive Officers**" means the ** of Rigel and the ** of Kissei, who have valid and sufficient authority.

1.51 "**Export Control Laws**" means all applicable U.S. laws and regulations relating to (a) sanctions and embargoes imposed by the Office of Foreign Assets Control of the U.S. Department of Treasury or (b) the export or re-export of commodities, technologies, or services, including the Export Administration Act of 1979, 24 U.S.C. §§ 2401-2420, the International Emergency Economic Powers Act, 50 U.S.C. §§ 1701-1706, the Trading with the Enemy Act, 50 U.S.C. §§ 1 et. seq., the Arms Export Control Act, 22 U.S.C. §§ 2778 and 2779, and the International Boycott Provisions of Section 999 of the U.S. Internal Revenue Code of 1986, in each case, as amended.

1.52 "**Extended Commercialization Term**" means the period commencing on the expiration of the Commercialization Term and extending for the period of time during which Rigel continues to supply to Kissei the Product under the Supply Agreement.

1.53 "**FCPA**" means the U.S. Foreign Corrupt Practices Act (15 U.S.C. Section 78dd-1, et. seq.), as amended.

1.54 "**FD&C Act**" means the Federal Food, Drug, and Cosmetic Act, as amended, and any regulations promulgated by the FDA thereunder.

1.55 "**FDA**" means the U.S. Food and Drug Administration and any successor Regulatory Authority having substantially the same function.

1.56 "**Field**" means all human diseases.

1.57 "**First Commercial Sale**" means, with respect to a country, the first sale for end use or consumption of a Product in such country that results in a Net Sale after all Regulatory Approvals legally required for such sale have been granted by the Regulatory Authority of such country.

1.58 "**FTE**" means the equivalent of a full-time individual's work for a twelve (12) month period (consisting of a total of ** per year of dedicated effort). Any person who devotes more or less than ** per year on the applicable activities shall be treated as an FTE on a pro-rata basis, based upon the actual number of hours worked by such person on such activities, divided by **. For clarity, the hours spent by temporary workers and contractors on applicable activities may be treated as FTE on a pro-rata basis.

1.59 "**FTE Rate**" means an initial rate of (a) with respect to Rigel's personnel, ** per FTE per year and (b) with respect to Kissei's personnel, **. Thereafter, the FTE Rate shall be changed annually on a Calendar Year basis to reflect any year-to-year percentage increase or decrease (as the case may be) (x) with respect to Rigel, in the **, and (y) with respect to Kissei, in the ** (both changes based on the change from the most recent applicable index available as of the Effective Date to the most recent applicable index available as of the date of the calculation of such revised FTE Rate).

1.60 "**GAAP**" means generally accepted accounting principles as practiced in the U.S., consistently applied.

1.61 "**GCP**" or "**Good Clinical Practices**" means the then-current good clinical practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials to assure that clinical trial results are credible and accurate and to protect the rights, integrity, and confidentiality of clinical trial subjects, including, as applicable, the U.S. regulations set forth in 21 C.F.R. Parts 50 ("Protection of Human Subjects"), 54 ("Financial Disclosure by Clinical Investigators"), 56 ("Institutional Review Boards"), and 312 ("Investigational New Drug Application"), as may be amended from time to time, and analogous Laws or regulations administered or promulgated by applicable Regulatory Authorities in any other relevant country or jurisdiction, as may be amended from time to time and to the extent such standards are not less stringent than U.S. GCP standards.

1.62 "**Generic Product**" means, with respect to a particular Product in a country or jurisdiction, a pharmaceutical product that is approved for use in such country or jurisdiction by a Regulatory Authority through a regulatory pathway referencing or relying on data and information in the Regulatory Approval for a Product, (including any such pharmaceutical product that has been approved for marketing in the U.S. pursuant to 21 U.S.C. § 505 (b)(2)), other than any Product that has been Developed under this Agreement by Kissei or any of its Affiliates or Sublicensees or Commercialized by Kissei or any of its Affiliates or Sublicensees in such country.

1.63 "**GLP**" or "**Good Laboratory Practices**" means the then-current good laboratory practice standards for conducting nonclinical studies that are intended to support applications for Regulatory Approval, including, as applicable, the U.S. regulations set forth in 21 C.F.R. Part 58, and analogous Laws or regulations administered or promulgated by applicable Regulatory Authorities in any other relevant country or jurisdiction, to the extent such standards are not less stringent than U.S. GLP standards.

1.64 "**GMP**" or "**Good Manufacturing Practices**" means the then-current good manufacturing practices that apply to the manufacturing, including clinical or commercial supply, of any Product or component thereof, including, as applicable, the U.S. regulations set forth in under Title 21 of the Code of Federal Regulations (C.F.R.), Parts 4, 210 and 211, as may be amended from time-to-time, and analogous Laws or regulations administered or promulgated by applicable Regulatory Authorities in any other relevant country or jurisdiction, as may be amended from time to time, and to the extent such standards are not less stringent than U.S. GMP standards.

1.65 "**Governmental Authority**" means any applicable governmental authority, court, tribunal, arbitrator, agency, department, legislative body, commission or other instrumentality of (a) any government of any country or territory, (b) any nation, state, province, county, city or other political subdivision thereof or (c) any supranational body.

1.66 "**ICH**" means the International Council for Harmonization (of Technical Requirements for Pharmaceuticals for Human Use).

1.67 "**IDH1**" means isocitrate dehydrogenase 1.

1.68 "**IND**" means an Investigational New Drug Application, as defined in the FD&C Act , together with any rules and regulations promulgated thereunder, or similar application or submission that is required to be filed with any Regulatory Authority anywhere in the world before beginning clinical testing of an investigational drug or biological product in human subjects, and in either case, any amendments or supplements thereto.

1.69 "**Indemnitee**" has the meaning set forth in Section 11.3.

1.70 "**Indemnitor**" has the meaning set forth in Section 11.3.

1.71 "**Indication**" means a separate and distinct disease, disorder, illness, or health condition and all of its associated signs, symptoms, stages, or progression (including precursor conditions) as stated (or would be stated) in the package insert for a product in the Kissei Territory. For clarity, subpopulations of patients with a primary disease or condition, however stratified (including stratification by stages or progression, particular combinations of symptoms associated with the primary disease or condition, prior treatment courses, response to prior treatment, family history, clinical history, phenotype, or the presence or absence of biomarkers) shall not be deemed to be separate "Indications" for the purposes of this Agreement.

1.72 "**Inventions**" means all inventions, whether or not patentable, discovered, made, conceived, or reduced to practice in the course of activities contemplated by this Agreement.

1.73 "**Initial Development Plan**" has the meaning set forth in Section 4.3.

1.74 "**Initial Indication**" means relapsed/refractory (R/R) AML.

1.75 "**Invent**" means the act of invention by inventors, as determined in accordance with the patent laws of the U.S.

1.76 "**Joint Inventions**" has the meaning set forth in Section 9.1.2(a).

1.77 "**Joint Know-How**" means any Know-How that is discovered, made or developed jointly in connection with the activities undertaken under this Agreement by one or more employees of Rigel or its Affiliates (or a Third Party acting on any of their behalf) and one or more employees of Kissei, its Affiliates or any Sublicensees (or a Third Party acting on any of their behalf).

1.78 "**Joint Patents**" means any Patent that is Invented jointly in connection with the activities undertaken under this Agreement by one or more employees of Rigel or its Affiliates (or a Third Party acting on any of their behalf) together with one or more employees of Kissei, its Affiliates or any Sublicensees (or a Third Party acting on any of their behalf).

1.79 "**Joint Technology**" means Joint Know-How and Joint Patents.

1.80 "**Joint Steering Committee**" or "**JSC**" means the Joint Steering Committee as more fully described in Section 3.1.

1.81 "**Kissei**" has the meaning set forth in the Preamble.

1.82 "**Kissei Data**" has the meaning set forth in Section 9.1.1.

1.83 "**Kissei Indemnitees**" has the meaning set forth in Section 11.1.

1.84 "**Kissei Know-How**" means Know-How Controlled by Kissei or its Affiliates on the Effective Date or during the Term that is necessary or reasonably useful to use, research, Develop, Manufacture or Commercialize Olutasidenib or the Products, but excluding Joint Know-How.

1.85 "**Kissei New Product Reimbursement**" has the meaning set forth in Section 2.2.

1.86 "**Kissei Patents**" means any Patent Controlled by Kissei or its Affiliates on the Effective Date or during the Term that is necessary or useful to use, research, Develop, Manufacture or Commercialize Olutasidenib or the Products, but excluding Joint Patents.

1.87 "**Kissei Product Mark**" has the meaning set forth in Section 9.5.1.

1.88 "**Kissei Technology**" means Kissei Know-How and Kissei Patents, including Kissei's interest in the Joint Inventions and Joint Patents.

1.89 "**Kissei Territory**" means Japan and, subject to Section 8.5, Republic of Korea and Taiwan.

1.90 "**Know-How**" means all chemical or biological materials and other tangible materials, inventions, improvements, practices, discoveries, developments, data, information, regulatory materials including Regulatory Filings, Regulatory Data, technology, methods, protocols, formulas, knowledge, know-how, trade secrets, processes, assays, skills, experience, techniques and results of experimentation and testing, including pharmacological, toxicological, research, pre-clinical and clinical data and analytical and quality control data, in all cases, whether or not confidential, proprietary or patentable, in written, electronic or any other form now known or hereafter developed, including any physical embodiments of any of the foregoing; but excluding in any event any Patent.

1.91 "**Losses**" has the meaning set forth in Section 11.1.

1.92 "**MAA**" means a marketing authorization application or equivalent application, and all amendments and supplements thereto, filed with the applicable Regulatory Authority in any country or jurisdiction. For clarity, MAA does not include any application for Pricing and Reimbursement Approval.

1.93 "**MAA Approval**" means approval of an MAA by the applicable Regulatory Authority for marketing and sale of a Product in the applicable country or jurisdiction, but excluding any Pricing and Reimbursement Approval.

1.94 "**Manufacturing**" or "**Manufacture**" means, as applicable, all activities associated with the production, manufacture, process of formulating, processing, purifying, filling, finishing, packaging, labeling, shipping, importing, exporting and storage of Products, and any part or component thereof, including process development, process validation, stability testing, manufacturing scale-up, pre-clinical, clinical and commercial manufacture and analytical development, product characterization, quality assurance and quality control, testing and release.

1.95 "**Medical Affairs**" means activities designed to ensure or improve appropriate medical use of, conduct medical education of, or further research regarding, the Product, including by way of example: (a) activities of medical scientific liaisons who, among their other functions, may: (i) conduct service based medical activities including providing input and assistance with consultancy meetings, proposing investigators for clinical trials sponsored or co-sponsored by a Party or Affiliate, and providing input in the design of such trials and other research related activities; and/or (ii) deliver non-promotional communications and conduct non-promotional activities; (b) grants to support continuing medical education, symposia, or Third Party research related to the Product; (c) development, publication, and dissemination of publications relating to the Product; (d) medical information services provided in response to inquiries communicated via sales representatives or received by letter, phone call, or email; (e) conducting advisory board meetings, international advisory board activities, or other consultant programs, including the engagement of key opinion leaders and health care professional in individual or group advisory and consulting arrangements; and (f) the evaluation of applications submitted to Kissei for support of investigator-initiated trials.

1.96 "**mIDH1**" means mutant isocitrate dehydrogenase 1.

1.97 "**mIDH2**" means mutant isocitrate dehydrogenase 2.

1.98 "**NDA**" means a New Drug Application, as defined in the FD&C Act and applicable regulations promulgated thereunder by the FDA, or any analogous application or submission with any Regulatory Authority in a relevant country or jurisdiction outside of the U.S., and in either case, any amendments or supplements thereto.

1.99 "**New Product**" means any compound or product that is a derivative of or new formulation of Olutasidenib as compared to the formulation of Olutasidenib in the Product as of the Effective Date.

1.100 "**Net Sales**" means, with respect to a Product, the aggregate gross invoiced sales prices from sales of all units of such Product sold by Kissei and its Related Parties to independent Third Parties in accordance with GAAP after deducting, if not previously deducted, from the amount invoiced or received:

(a) trade, quantity and cash discounts, credits or allowances actually given;

(b) allowances for returns or rejections (due to spoilage, damage, expiration of useful life or otherwise);

(c) freight and insurance, if separately identified on the invoice;

(d) Third Party rebates, chargebacks, hospital buying group/group purchasing organization administration fees or managed care organization rebates actually given and other similar administrative fees, rebates and allowances granted to any non-related party, including to Governmental Authorities, purchasers, reimbursors, customers, distributors and wholesalers;(e) value-added tax, sales, use or turnover taxes, excise taxes and customs duties assessed by Governmental Authorities on the sale of the Product;

(f) retroactive price reductions or billing corrections.

In the case of any sale or other disposal for value, such as barter or counter-trade, of a Product, or part thereof, other than in an arm's length transaction exclusively for cash, Net Sales shall be calculated as above on the value of the non-cash consideration received or the fair market price (if higher) of such Product in the country of sale or disposal, as determined in accordance with GAAP.

For clarity, named-patient sales shall be included in "Net Sales".

Notwithstanding the foregoing, the following shall not be included in Net Sales: (i) sales between or among Kissei and its Related Parties (but Net Sales shall include sales to the first Third Party (other than a Sublicensee) by Kissei or its Related Parties); and (ii) samples of Product used to promote additional Net Sales, in amounts consistent with normal business practices of Kissei or its Related Parties where the Product is supplied without charge or at or below the actual manufacturing cost thereof (without allocation of indirect costs or any mark-up).

In the event that a Product is sold as a Combination Product, Net Sales, for the purposes of determining royalty payments on the Combination Product, means the aggregate gross invoiced sales prices from sales of all units of such Combination Product sold by a Party and its Related Parties to independent Third Parties in accordance with GAAP less the deductions set forth in clauses (a) – (f) above, multiplied by a proration factor that is determined as follows:

(A) If the Product and the other Active Ingredients in such Combination Product are both sold separately during the same or immediately preceding Calendar Quarter, then Net Sales for the Product shall be calculated by multiplying actual Net Sales of such Combination Product during such period by the fraction A/(A+B), where: "A" is the average gross invoiced sales price of the Product during such period when sold separately in the same formulation and dosage; and "B" is the average gross invoiced sales price of the Active Ingredients contained in the Combination Product during such period when sold separately in the same formulation and dosage.

(B) If the Product is sold separately during the same or immediately preceding Calendar Quarter in the same formulation and dosage as in the Combination Product, but the other Active Ingredients contained in the Combination Product are not sold separately during such period in the same formulation and dosage as in the Combination Product, then Net Sales for the Product shall be calculated by multiplying actual Net Sales of such Combination Product during such period by the fraction A/C, where "A" is the average gross invoiced sales price of the Product during such period when sold separately in the same formulation and dosage and "C" is the average gross invoiced sales price of the Combination Product during such period;

(C) If the Product is not sold separately during the same or immediately preceding Calendar Quarter in the same formulation and dosage as in the Combination Product, but the other Active Ingredients contained in the Combination Product are sold separately during such period in the same formulation and dosage as in the Combination Product, then Net Sales for the Product shall be calculated by multiplying actual Net Sales of such Combination Product by the result of 1 – (B/C), where "B" is the average gross invoiced sales price of the other Active Ingredients contained in the Combination Product during such period when sold separately in the same formulation and dosage and "C" is the average gross invoiced sales price of the Combination Product during such period; or

(D) If neither the Product nor the other Active Ingredients contained in the Combination Product were not sold separately during the same or immediately preceding Calendar Quarter, the proration factor shall be determined by the Parties in good faith negotiations based on the relative value contributed by each component.

1.101 "**Olutasidenib**" means olutasidenib, a proprietary mIDH1 inhibitor, also referred to as FT-2102, (S)-5-((1-(6-chloro-2-oxo-1,2-dihydroquinolin-3-yl)ethyl)amino)-1-methyl-6-oxo-1,6-dihydropyridine-2-

carbonitrile, or 5-{[(1S)-1-(6-chloro-2-oxo-1,2-dihydroquinolin-3-yl)ethyl]amino}-1-methyl-6-oxo-1,6-dihydropyridine-2-carbonitrile.

1.102 "**Party**" and "**Parties**" have the meaning set forth in the Preamble.

1.103 "**Patents**" means (a) all issued patents (including any extensions, restorations by any existing or future extension or registration mechanism including patent term adjustments, patent term extensions, supplemental protection certificates or the equivalent thereof, substitutions, confirmations, re-registrations, re-examinations, reissues, patents and patent claims maintained after post grant examination including *inter partes* review, post grant review or opposition proceeding and patents of addition); (b) patent applications (including all provisional applications, substitutions, requests for continuation, continuations, continuations-in-part, divisionals and renewals); (c) inventor's certificates; and (d) all equivalents and counterparts of the foregoing in any country of the world.

1.104 "**Person**" means any natural person, corporation, unincorporated organization, partnership, association, sole proprietorship, joint stock company, joint venture, limited liability company, trust or government, or Governmental Authority, or any other similar entity.

1.105 "**Permissible Delay**" has the meaning set forth in Section 4.2.2(a).

1.106 "**Pharmacovigilance Agreement**" has the meaning set forth in Section 5.6.

1.107 "**Phase 3 Clinical Study**" means a Clinical Study in any country that would satisfy the requirements of U.S. 21 C.F.R. Part 312.21(c) and is intended to: (a) establish that the Product is safe and efficacious for its intended use; (b) define contraindications, warnings, precautions, and adverse reactions that are associated with the Product in the dosage range to be prescribed; and (c) support Regulatory Approval for such Product, or a similar clinical study prescribed by the relevant Regulatory Authorities in a country other than the U.S.

1.108 "**Post-Approval Commitments**" means any post-approval commitments, including any non-clinical study or Clinical Study of a Product, required by a Regulatory Authority in a country or territory in connection with the Regulatory Approval for such Product in such country or jurisdiction.

1.109 "**PMDA**" **means** Japan's Pharmaceuticals and Medical Devices Agency or its successor.

1.110 "**Pricing and Reimbursement Approval**" means, with respect to a Product, the approval, agreement, determination or decision of any Regulatory Authority establishing the price or level of reimbursement for such Product, as required in a given country or jurisdiction prior to sale of such Product in such country or jurisdiction.

1.111 "**Product**" means the Olutasidenib product described in the U.S. Regulatory Approval for Olutasidenib in existence as of the Effective Date.

1.112 "**Product Infringement**" has the meaning set forth in Section 9.3.1.

1.113 "**Public Official or Entity**" means (a) any officer, employee (including physicians, hospital administrators, or other healthcare professionals), agent, representative, department, agency, de facto official, representative, corporate entity, instrumentality, or subdivision of any government, military, or international organization, including any ministry or department of health or any state-owned or affiliated company or hospital, or (b) any candidate for political office, any political party, or any official of a political party.

1.114 "**Publication Materials**" has the meaning set forth in Section 12.4.1.

1.115 "**Publishing Party**" has the meaning set forth in Section 12.4.1.

1.116 "**Recall**" has the meaning set forth in Section 5.9.

1.117 "**Registrational Study**" means (a) Phase 3 Clinical Study or (b) any other Clinical Study (including a portion of a study, such as the Phase 3 Clinical Study portion of a Phase 2b/3 study) of a Product, the results of which, together with prior data and information concerning such Product, would (if such Clinical Study meets its primary endpoints) be sufficient to support Regulatory Approval by the FDA for such Product without the need to conduct additional Clinical Studies, or a similar Clinical Study prescribed by the Regulatory Authority in a country or jurisdiction other than the U.S. With respect to a Clinical Study that does not meet the foregoing criteria when it is initiated but, at a later time, for which the applicable Regulatory Authority determines that such Clinical Study meets the foregoing criteria and Kissei files an NDA using the data generated by such Clinical Study as the basis for such filing, such Clinical Study shall be deemed a Registrational Study for purposes of this Agreement as of the date of

filing of such NDA, and, for purposes of this Agreement, such Registrational Study shall be deemed to be initiated as of the date of such determination.

1.118 "**Regulatory Approval**" means, with respect to any country or region in the Kissei Territory, any approval (including approval of an NDA), establishment license, registration, permit, notification or authorization (or waivers) of any Regulatory Authority that is required by applicable Laws for the manufacture, use, storage, import, export, transport, promotion, marketing, distribution, offer for sale, sale or other Commercialization of a Product in such country or region, including Pricing and Reimbursement Approval, as applicable.

1.119 "**Regulatory Authority**" means any national, international, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity with authority over the approval, distribution, importation, exportation, manufacture, use, storage, transport, clinical testing, pricing, sale or reimbursement of pharmaceutical products in the Kissei Territory.

1.120 "**Regulatory Data**" means any and all research data, pharmacology data, CMC Data, Safety Data, preclinical data, clinical data and all other documentation submitted, or required to be submitted, to Regulatory Authorities in association with Regulatory Filings and Regulatory Approvals for the Products (including any applicable drug master files or similar documentation).

1.121 "**Regulatory Exclusivity**" means, with respect to any Product in any country or jurisdiction in the Kissei Territory, the period of time during which: (a) Kissei, its Affiliate, or a Sublicensee has the exclusive legal right, pursuant to a grant by a Regulatory Authority, other than through a Patent, including orphan drug exclusivity, new chemical entity exclusivity, pediatric exclusivity, or rights similar thereto in such country or jurisdiction, or is otherwise entitled to the exclusive legal right by operation of Applicable Laws in such country or jurisdiction to Commercialize such Product, and such right precludes the final Regulatory Approval of any Third Party product that is deemed to be the same or a similar drug; or (b) the data and information submitted by Kissei, its Affiliate, or any Sublicensee to the relevant Regulatory Authority in such country or jurisdiction for purposes of obtaining Regulatory Approval of such Product may not be disclosed, referenced, or relied upon in any way by any Third Party or such Regulatory Authority to support the Regulatory Approval or marketing of any product by any Third Party in such country or jurisdiction, or if such data and information is disclosed, referenced, or relied upon to support a Regulatory Approval granted to any Third Party in such country or jurisdiction, then the product may not be placed on the market for any indication.

1.122 "**Regulatory Filing**" means any documentation comprising or relating to or supporting any filing or application with any Regulatory Authority with respect to any Product, or its use or potential use in humans, including any documents submitted to any Regulatory Authority and all supporting data, including INDs, clinical trial applications and NDAs, and all correspondence with any Regulatory Authority with respect to such Product (including minutes of any meetings, telephone conferences or discussions with any Regulatory Authority).

1.123 "**Reviewing Party**" has the meaning set forth in Section 12.4.2.

1.124 "**Related Parties**" means a Party's Affiliates and Sublicensees.

1.125 "**Rigel**" has the meaning set forth in the Preamble.

1.126 "**Rigel Data**" has the meaning set forth in Section 9.1.1.

1.127 "**Rigel-Forma Agreement**" is defined in the Recitals.

1.128 "**Rigel Indemnitee**" has the meaning set forth in Section 11.2.

1.129 "**Rigel Know-How**" means Know-How Controlled by Rigel or its Affiliates on the Effective Date or during the Term that is necessary or reasonably useful to Develop or Commercialize the Products in the Field in the Kissei Territory, including any such Know-How that is licensed to Rigel under the Rigel-Forma Agreement, but excluding Joint Know-How.

1.130 "**Rigel Patents**" means any Patent Controlled by Rigel or its Affiliates on the Effective Date or during the Term that is necessary or useful to Develop or Commercialize the Products in the Field in the Kissei Territory, including any such Patent that is licensed to Rigel under the Rigel-Forma Agreement, but excluding Joint Patents. The Rigel Patents existing as of the Effective Date are those Patents identified on Schedule 10.3.1, attached hereto and incorporated herein by reference.

1.131 "**Rigel Technology**" means Rigel Know-How and Rigel Patents, including Rigel's interest in the Joint Inventions and Joint Patents.

1.132 "**Rigel Territory**" means the world outside the Kissei Territory.

1.133 "**Rigel Third Party In-License**" is defined in Section 1.37.

1.134 "**Rigel Product Marks**" means the Product Marks that are Controlled by Rigel or its Affiliates on the Effective Date, including any such Trademark that is licensed to Rigel under the Rigel-Forma Agreement. The Rigel Product Marks existing as of the Effective Date are those Trademarks identified on Schedule 1.134, attached hereto and incorporated herein by reference.

1.135 "**Safety Data**" means any adverse event (as such term is used in the meaning set forth in 21 C.F.R. § 312.32 or its equivalents in the Kissei Territory) information from human trials and all results from non-clinical safety studies, including toxicology and safety pharmacology data, with respect to a Product required by one or more Regulatory Authorities to be collected or to be reported to such Regulatory Authorities under applicable Laws, but excluding any information related to the efficacy of the Products.

1.136 "**SEC**" means the U.S. Securities and Exchange Commission, or any successor entity or its foreign equivalent, such as the Japan Exchange Group (JPX), as applicable.

1.137 "**Sublicense Revenue**" means any consideration ** that Kissei or its Affiliates receives from a Third Party Sublicensee as consideration for, and solely to the extent attributable to, the grant of a Sublicense to Develop and Commercialize the Product in the Republic of Korea and/or Taiwan but excluding Japan, or an option to obtain such Sublicense, ** for Kissei's research and Development activities. Sublicense Revenue excludes (i) **, (ii) and (iii) ** Kissei or its Affiliates ** included as "**Sublicense Revenue**" hereunder.

1.138 "**Sublicense**" means any grant by Kissei to an Affiliate or a Third Party of any of the licenses or rights granted under this Agreement or any part thereof, including the right to Develop or Commercialize any Product, in accordance with Section 2.1.2.

1.139 "**Sublicensee**" means a Third Party to whom Kissei grants a direct or indirect sublicense under any Rigel Technology or Joint Technology, as the case may be, to Develop or Commercialize a Product in the Field in the Kissei Territory pursuant to Section 2.1.2.

1.140 "**Sunshine Reporting Laws**" has the meaning set forth in Section 5.10.

1.141 "**Supply Agreement**" has the meaning set forth in Section 7.3.

1.142 "**Term**" has the meaning set forth in Section 13.1.

1.143 "**Third Party**" means a Person other than a Party and its Affiliates.

1.144 "**Trademark**" means any trademark, trade name, service mark, service name, brand, domain name, trade dress, logo, slogan or other indicia of origin or ownership, including the goodwill and activities associated with each of the foregoing.

1.145 "**Transfer Price**" has the meaning set forth in Section 8.4.1(a).

1.146 "**Transfer Price Rate**" has the meaning set forth in Section 8.4.1(a).

1.147 "**United States**" or "**U.S.**" means the United States of America and its territories, possessions and commonwealths.

1.148 "**Valid Claim**" means any claim of a Patent included within the Rigel Patents or Joint Patents that (a) has been granted by a patent granting authority, that is in force, and that has not been surrendered, abandoned, revoked or held invalid or unenforceable by an unappealed or unappealable decision taken by an administrative or civil court in a jurisdiction, or (b) a pending claim in a Patent application included within the Rigel Patents or Joint Patents which is filed in good faith **.

1.149 "**wtIDH1**" means wild-type isocitrate dehydrogenase 1.

2. LICENSES; EXCLUSIVITY

2.1 License Grants to Kissei.

2.1.1 Exclusive License Grant. Subject to the terms and conditions of this Agreement (including Section 2.3), Rigel hereby grants to Kissei a non-transferable (except as provided in Section 15.5), sublicensable (subject to Section 2.1.2), exclusive (even as to Rigel and its Affiliates, but subject to Section 2.3), license under the Rigel Technology and Rigel's interest in the Joint Technology to Develop and Commercialize (but not to make, have made, Manufacture or have Manufactured) the Products in the Field in the Kissei Territory. The license granted hereunder shall be royalty-bearing for the Commercialization Term applicable to each Product in the Kissei Territory, and, after the Commercialization Term applicable to such Product, shall convert on a country-by-country basis, to a fully-paid-up, royalty-free perpetual and irrevocable license. For clarity, the license granted hereunder does not include any New Product. Notwithstanding the preceding sentence, Kissei shall have the right to Develop and Commercialize new formulations of olutasidenib in the Kissei Territory with the prior written consent of Rigel, which consent shall not be unreasonably withheld or delayed and may require the negotiation of additional terms under this Agreement.

2.1.2 Kissei Sublicense Rights.

(a) Kissei shall have the right to sublicense any of its rights under Section 2.1.1 to (a) any of its Affiliates with the express prior consent of Rigel (provided that such sublicense will terminate if such sublicensee no longer qualifies as an Affiliate of Kissei) or (b) to any Third Party with the express prior consent of Rigel (such consent not to unreasonably withheld, conditioned or delayed), subject to the requirements of this Section 2.1.2. For clarity, Kissei may not sublicense any of its rights under Section 2.1.1 to an Affiliate or Third Party for use by such Affiliate or Third Party to develop, manufacture or commercialize a Generic Product to a Product.

(b) Each sublicense granted by Kissei pursuant to this Section 2.1.2 shall be in writing, shall be subject and subordinate to, and consistent with, the terms of this Agreement, and shall provide that any such Sublicensee (for clarity, including any distributor, but not including any contract research organization engaged to conduct Development activities) shall not further sublicense except with the consent of Kissei and Rigel, which consent shall not be unreasonably withheld or delayed. Kissei shall promptly provide Rigel with a copy of each fully executed sublicense agreement covering any sublicense granted hereunder, and each such sublicense agreement shall contain the following provisions: (a) a requirement that the Sublicensee comply with confidentiality and non-use provisions that are equivalent to those described in Article 12 with respect to Rigel's Confidential Information, and (b) a requirement that the Sublicensee submit applicable sales or other reports to Kissei to the extent necessary or relevant to the reports required to be made or records required to be maintained under this Agreement. Kissei shall ensure that each agreement with a Sublicensee grants Rigel all rights with respect to Data, Inventions, and Regulatory Filings made or generated by such Sublicensee as if such Data, Inventions, and Regulatory Filings were made or generated by Kissei. Notwithstanding any sublicense, Kissei shall be responsible and liable for the compliance of its Affiliates, Sublicensees (for clarity, including any distributors and contract research organization engaged to conduct Development activities), and their subcontractors with the terms and conditions of this Agreement.

2.1.3 Trademarks. Kissei has the right to use the Rigel Product Marks in a manner consistent with this Agreement and the trademark usage guidelines provided by Rigel prior to or as of the Effective Date and, with respect to such provided guidelines, as updated in writing from time-to-time. Kissei shall not use any marks that are confusingly similar to a Rigel Product Mark in a country in which Rigel holds such Trademark. All rights in each of the Rigel Product Marks shall remain at all times the sole property of Rigel, and all use of such Rigel Product Marks shall inure to the benefit of Rigel. Kissei agrees not to contest Rigel's ownership of the Rigel Product Marks.

2.2 Kissei Option for New Products in the Kissei Territory. Rigel shall disclose to Kissei any New Product which Rigel wishes to outlicense. Kissei shall have the option to negotiate with Rigel for a license to Develop and Commercialize ** any New Product in the Field in the Kissei Territory by agreement between the Parties **. Kissei would pay Rigel for costs incurred by Rigel with respect to such New Product ("**Kissei New Product Reimbursement**") after reaching such agreement during the Exclusive Negotiation Period (defined below), through amending this Agreement or entering into a separate agreement, which includes payment terms for such Kissei New Product Reimbursement. Such first right shall commence on the date such New Product is disclosed by Rigel to Kissei in writing and expire ** thereafter (the "**Exclusive Negotiation Period**"). During the Exclusive Negotiation Period, Rigel and Kissei shall negotiate exclusively with respect to any New Product in the Field in the Kissei Territory and in good faith the relevant terms (including the Kissei New Product Reimbursement) for licensing such New Product.

If Rigel and Kissei do not agree to terms for licensing such New Product hereunder, then Rigel would not have the right to Develop, Commercialize or out-license to any third party, such New Product in the Kissei Territory. For clarity, at any time (including during the Exclusive Negotiation Period and thereafter), Rigel shall have the right to license any New Product to any Third Party in the Rigel Territory without any further obligation to Kissei.

2.3 Retained Rights by Rigel. Notwithstanding the provisions of Section 2.1 or any other provision of this Agreement, Rigel shall retain rights under the Rigel Technology and Joint Technology to (a) exercise its rights and perform its obligations under this Agreement (whether directly or through one or more licensees or subcontractors), (b) Develop the Product in the Kissei Territory (whether in or outside the Field) solely for the purpose of supporting obtaining Regulatory Approval and Commercializing such Products in the Rigel Territory, and (c) subject to Kissei's rights under Section 2.2 with respect to New Products, practice, and to grant licenses under, the Rigel Technology and Joint Technology outside of the scope of the licenses granted in Section 2.1.

2.4 Licenses Grants to Rigel.

2.4.1 License Grants. Subject to the terms and conditions of this Agreement, Kissei hereby grants to Rigel: (i) a transferrable, sublicensable (through multiple tiers, subject to Section 2.4.2), exclusive (even as to Kissei and its Affiliates), royalty-free, fully paid-up, perpetual and irrevocable license under the Kissei Technology and Kissei's interest in the Joint Technology to use, research, Develop and Commercialize Olutasidenib, the Products and New Products in the Rigel Territory; (ii) a transferrable, sublicensable (through multiple tiers, subject to Section 2.4.2), co-exclusive (as to any Third Party but not Kissei or its Affiliates) , royalty-free, fully paid up, perpetual, and irrevocable license under the Kissei Technology and Kissei's interest in the Joint Technology to Develop New Products in the Kissei Territory; and (iii) a transferrable, sublicensable (through multiple tiers, subject to Section 2.4.2), exclusive (even as to Kissei and its Affiliates) , royalty-free, fully paid-up, perpetual and irrevocable license under the Kissei Technology and Kissei's interest in the Joint Technology to Manufacture Olutasidenib, the Products and New Products anywhere in the world. Notwithstanding the foregoing, Rigel shall obtain the prior written approval of Kissei to undertake (ii) or (iii) above in the Kissei Territory, such approval not to be unreasonably withheld, conditioned or delayed.

2.4.2 Rigel Sublicense Rights. Rigel shall have the right to grant sublicenses under the licenses granted in Section 2.4.1(i) without Kissei's consent in the Rigel Territory, shall have the right to grant sublicenses under the licenses granted in Section 2.4.1(ii) with Kissei's prior written consent in the Kissei Territory, which consent shall not be unreasonably withheld or delayed, and shall have the right to grant sublicenses under the licenses granted in Section 2.4.1(iii) without Kissei's consent anywhere in the world. Rigel shall be responsible and liable for the compliance of its Affiliates, Sublicensees (for clarity, including any distributors and contract research organization for its Development), and subcontractors with the terms and conditions of this Agreement.

2.5 Retained Rights by Kissei. For the avoidance of doubt, notwithstanding the provisions of Section 2.4 or any other provision of this Agreement, Kissei shall retain rights under the Kissei Technology and Joint Technology to (a) exercise its rights and perform its obligations under this Agreement (whether directly or through one or more licensees or subcontractors), and (b) to practice, and to grant licenses under, the Kissei Technology and Joint Technology outside of the scope of the licenses granted in Section 2.4.

2.6 No Implied Licenses or Other Rights; Negative Covenant . Except as set forth in this Agreement, neither Party shall acquire any ownership interest, license or other intellectual property interest, or other right, by implication or otherwise, under or to any Patents, Know-How or other intellectual property of the other Party or any of its Affiliate, including items owned, controlled or developed by the other Party, or provided by the other Party to such Party at any time pursuant to this Agreement. Neither Party shall, nor shall it permit any of its Affiliates or Sublicensees to, practice any Patents, Know-How, or other intellectual property licensed to it by the other Party outside the scope of the licenses expressly granted to it under this Agreement.

2.7 Disclosure of Know-How. For as long as the Parties are conducting Development activities, each Party shall and shall cause its Affiliates to, without additional compensation, disclose and make available to other Party, in electronic form where possible, all such Party's Know-How that comes into existence after the Effective Date and that was not previously provided to the other Party, promptly after the development, making, conception, or reduction to practice of such Party's Know-How. The JSC shall establish a mechanism for the timely reciprocal disclosure of such Know-How.

2.8 Third Party Licenses.

2.8.1 Kissei Third Party Licenses. Kissei shall promptly notify Rigel if Kissei becomes aware of any Third Party Know-How or Patent that is necessary or reasonably useful to Develop, Manufacture or Commercialize the Product in the Field in the Kissei Territory, and Rigel shall have the first right, but not the obligation, to negotiate and obtain a license from such Third Party under such Know-How or Patents, provided that Rigel shall, subject to any applicable confidentiality obligations, keep Kissei reasonably informed of the status of such negotiations.

2.8.2 Rigel Third Party Licenses. If Rigel enters into any agreement with any Third Party after the Effective Date that includes a license from such Third Party to Rigel under any Know-How or Patents that are necessary or reasonably useful to Develop or Commercialize the Products in the Field in the Kissei Territory, and Rigel has the right to grant a sublicense under such Know-How or Patents to Kissei, then Rigel shall notify Kissei and identify the relevant Know-How or Patents and provide Kissei with the substantive terms of the applicable Third Party license agreement to Kissei, in each case to the extent applicable to the rights that would be sublicensed to Kissei. Such Know-How and Patents, to the extent falling within the definition of Rigel Technology, will be sublicensed to Kissei only if Kissei provides Rigel with written notice ** such Patents and Know-How ** Rigel Technology, ** the Product in the Field in the Kissei Territory, ** in writing **.

2.8.3 Kissei Restriction. Except with the prior written consent of Rigel, Kissei shall not obtain a license to any Third Party Patent or Know-How that is necessary or reasonably useful to Develop, Manufacture or Commercialize the Product in the Rigel Territory.

2.9 Exclusivity.

2.9.1 For the period starting from the Effective Date and until (i) the ** of the first Regulatory Approval of the Product in the Kissei Territory, Kissei shall not, directly or indirectly (including through an Affiliate or a Third Party), ** any Competing Product and (ii) the ** of the first Regulatory Approval of the Product in the Kissei Territory, Kissei shall not, and shall cause its Affiliates not to, directly or indirectly (including through an Affiliate or a Third Party) ** any Competing Product (each such activity, a "**Competing Program**").

2.9.2 In the event that a Third Party becomes an assignee of this Agreement or an Affiliate of Kissei after the Effective Date through merger, acquisition, consolidation, or other similar transaction, and such Third Party, as of the closing date of such transaction, is engaged in the conduct of a Competing Program, then Rigel shall have the right to terminate this Agreement upon immediate written notice to Kissei if, within ** after the closing of such transaction, such Third Party does not completely Divest such Competing Program. "**Divest**" means the sale or transfer of rights to the Competing Product to another Third Party (i.e., not an Affiliate of either Kissei or such Third Party) without receiving a continuing share of profit, royalty payment, or other economic interest in the success of such Competing Program.

2.9.3 During the Term, Kissei shall not, and shall cause its Affiliates not to, directly or indirectly (including through an Affiliate or a Third Party), Develop or Commercialize Olutasidenib or the Product in the Rigel Territory or any Generic Product of any Product anywhere in the world.

2.9.4 During the Term, Rigel shall not, and shall cause its Affiliates not to, directly or indirectly (including through an Affiliate or a Third Party), ** Olutasidenib or the Product outside the Field in the Kissei Territory.

2.9.5 For the period starting from the Effective Date and until (i) the ** of the first Regulatory Approval of the Product in the Kissei Territory, Rigel shall not, directly or indirectly (including through an Affiliate or a Third Party), ** any Competing Product in the Kissei Territory and (ii) the ** of the first Regulatory Approval of the Product in the Kissei Territory, Rigel shall not, and shall cause its Affiliates not to, directly or indirectly (including through an Affiliate or a Third Party) ** any Competing Product in the Kissei Territory. In the event that a Third

Party becomes an assignee of this Agreement or an Affiliate of Rigel after the Effective Date through merger, acquisition, consolidation, or other similar transaction, and such Third Party, as of the closing date of such transaction, is engaged or becomes engaged in Developing or Commercializing a Competing Product in the Kissei Territory, then Rigel shall, cause such Third Party to Segregate such Competing Program. "**Segregate**" means, with respect to a Competing Product being Developed or Commercialized in the Kissei Territory, to segregate the Development and Commercialization activities relating to such Competing Product conducted by or on behalf of such Third Party from the Development and Commercialization activities conducted by or on behalf of such Third Party with respect to the Product.

2.10 Complementary Products. In the event that Kissei Develops or Commercializes one (1) or more Complementary Products, the following shall apply: (a) for a ** the First Commercial Sale of the Product in the Kissei Territory, Kissei shall ensure that the Product has a priority detail position (i.e., first call or second call); (b) Kissei shall not ** disproportionately favours the Complementary Product; (c) Kissei shall not ** in a manner that is inconsistent with Kissei's customary practice for its products; and (d) in applying Commercially Reasonable Efforts in the Development or Commercialization of the Product**, Kissei shall not **.

3. GOVERNANCE

3.1 Joint Steering Committee. As of the Effective Date, the Parties have established a joint steering committee (the "**Joint Steering Committee**" or the "**JSC**"), composed of an equal number of up to ** senior employees of each Party, to oversee and guide the strategic direction of the collaboration of the Parties under this Agreement. The JSC shall act as a joint consultative body and, to the extent expressly provided herein, a joint decision-making body. The JSC shall in particular:

3.1.1 provide a forum for discussion of the Development and Commercialization of Olutasidenib, the Product and New Products in the Kissei Territory and the Rigel Territory;

3.1.2 review and discuss the global strategy for the Development of the Product worldwide,

3.1.3 coordinate and monitor activities under the Development Plan and oversee implementation of the Development Plan;

3.1.4 review and discuss any proposed amendments to the Development Plan;

3.1.5 provide a forum for and facilitate communications between the Parties with respect to sharing of Development information, Know-How, and Data in accordance with this Agreement;

3.1.6 review and discuss Clinical Study protocols and monitor the progress of all Clinical Studies in the Kissei Territory;

3.1.7 review Clinical Study Data in the Kissei Territory to determine whether progress to the next phase Clinical Study is merited;

3.1.8 review and discuss Development plans related to new Indications or formulations;

3.1.9 monitor and coordinate regulatory actions and pharmacovigilance and safety matters for the Product worldwide;

3.1.10 review and discuss a Party's concern that an action with respect to a Product could reasonably be expected to have a material adverse impact upon the regulatory status of such Product in such Party's territory in accordance with Section 5.7;

3.1.11 oversee and coordinate the Development of the New Products for use anywhere in the Kissei Territory, as well as analytical testing and other quality-related testing required in the Kissei Territory;

3.1.12 oversee and coordinate Medical Affairs for the Product in all Indications in the Kissei Territory;

3.1.13 review and discuss the Commercialization Plan for the Kissei Territory, including proposed amendments;

3.1.14 to the extent Kissei is participating in any global Registrational Study as further described in Section 4.1.2, share information regarding the strategy for the global Registrational Study;

3.1.15 review and discuss the clinical development strategy for the Product **, and oversee the development of the Product ** in the Kissei Territory;

3.1.16 review the manufacturing and supply strategy and supply performance;

3.1.17 oversee and facilitate the Parties' communications and activities with respect to publications under Section 12.4;

3.1.18 establish joint subcommittees as it deems necessary or advisable to further the purpose of this Agreement, including as set forth in Section 3.7; and

3.1.19 perform such other functions as appropriate to further the purposes of this Agreement, as expressly set forth in this Agreement or allocated to it by the Parties' written agreement.

3.2 JSC Membership and Meetings.

3.2.1 Committee Members; Minutes. Each JSC representative shall have appropriate knowledge and expertise and sufficient seniority within the applicable Party to make decisions arising within the scope of the JSC's responsibilities. Each Party may replace its representatives on the JSC on written notice to the other Party, but each Party shall strive to maintain continuity in the representation of its JSC members. The JSC chairperson shall **. The chairperson shall prepare and circulate agendas to JSC members at least ** before each JSC meeting and shall direct the preparation of reasonably detailed minutes for each JSC meeting, which minutes shall include, at a minimum, all decisions made by the JSC , and which shall be approved by the chairperson and circulated to JSC members within ** after such meeting. The Parties shall determine their respective initial members of the JSC promptly following the Effective Date.

3.2.2 Meetings. The JSC shall hold meetings at such times as it elects to do so, but in no event shall meetings of the JSC be held less frequently than ** prior to ** the Product in the Kissei Territory. The first JSC meeting shall be held within ** the Effective Date, at which meeting the dates for the first Calendar Year shall be set. JSC meetings may be held in person or by audio or video teleconference; provided that, unless otherwise agreed in writing by both Parties, at least ** shall be held in person. In-person JSC meetings shall be held at locations alternately selected by the Parties. Each Party shall be responsible for all of its own expenses of participating in any JSC meeting. No action taken at any JSC meeting shall be effective unless at least ** of each Party is participating. In addition, upon written notice to the other Party, either Party may request that a special *ad hoc* meeting of the JSC be convened for the purpose of resolving any disputes in connection with, or for the purpose of reviewing or making a decision pertaining to any material subject-matter within the scope of the JSC, the review or resolution of which cannot be reasonably postponed until the following scheduled JSC meeting. Such *ad hoc* meeting shall be convened at such time as may be mutually agreed by the Parties, but no later than ** following the notification date of request that such meeting be held.

3.2.3 Non-Member Attendance. Each Party may from time to time invite a reasonable number of participants, in addition to its representatives, to attend JSC meetings in a non-voting capacity; provided that if either Party intends to have any Third Party (including any consultant) attend such a meeting, such Party shall provide reasonable prior written notice to the other Party and obtain the other Party's approval for such Third Party to attend such meeting, which approval shall not be unreasonably withheld or delayed. Such Party shall ensure that such Third Party is bound by written confidentiality and non-use obligations consistent with the terms of this Agreement.

3.3 Decision-Making.

3.3.1 All decisions of the JSC shall be made by unanimous vote, with each Party's representatives collectively having one (1) vote. If after reasonable discussion and good faith consideration of each Party's view on a particular matter, the representatives of the Parties cannot reach an agreement as to such matter within ** such matter was brought to the JSC for resolution, then either Party at any time may refer such issue to the Executive Officers for resolution.

3.3.2 If the Executive Officers cannot resolve such matter within ** such matter has been referred to them, then:

(a) Rigel shall have the final decision-making authority, which shall be exercised in its reasonable discretion, with respect to any matters pertaining to (1) the Development or Commercialization of the Product in the Rigel Territory, and (2) the Development of the Product in the Kissei Territory that is conducted solely

by or on behalf of Rigel and, solely with respect to (2), that do not adversely affect and are not reasonably expected to adversely affect the Development or Commercialization of the Product in the Kissei Territory; provided that Rigel's decision with respect to any of the foregoing shall be consistent with the terms and conditions of this Agreement.

(b) Kissei shall have the final decision-making authority, which shall be exercised in its reasonable discretion, with respect to any matters pertaining to (1) the Commercialization of the Product in the Kissei Territory, (2) Medical Affairs in the Kissei Territory, (3) regulatory matters in the Kissei Territory, and (4) the Development of the Product in the Kissei Territory that is conducted solely by or on behalf of Kissei, in each case (1) - (4) that do not adversely affect and are not reasonably expected to adversely affect the Development, Manufacture or Commercialization of the Product in the Rigel Territory; provided that Kissei's decision with respect to any of the foregoing shall be consistent with the terms and conditions of this Agreement.

3.4 Limitations on Authority. The JSC shall have only such powers as are expressly assigned to it in this Agreement, and such powers shall be subject to the terms and conditions of this Agreement. Without limiting the generality of the foregoing, the JSC will not have the power to amend this Agreement, and no JSC decision may be in contravention of any terms and conditions of this Agreement.

3.5 Discontinuation of the JSC. The activities to be performed by the JSC shall solely relate to governance under this Agreement, and are not intended to be or involve the delivery of services. The JSC shall continue to exist until the first to occur of (a) the Parties mutually agree to disband the JSC; or (b) Rigel provides written notice to Kissei of its intention to disband and no longer participate in the JSC. Once the Parties mutually agree or Rigel has provided written notice to disband the JSC, the JSC shall have no further obligations under this Agreement and, thereafter, each Party shall designate a contact person for the exchange of information under this Agreement or such exchange of information shall be made through Alliance Managers, and decisions formerly assigned the JSC shall thereafter be decisions made between the Parties, subject to the other terms and conditions of this Agreement.

3.6 Alliance Managers. Promptly after the Effective Date, each Party shall appoint an individual who shall be an employee of such Party having appropriate qualification and experience to act as the alliance manager for such Party (the "**Alliance Manager**"). Each Alliance Manager shall be responsible for coordinating and managing processes and interfacing between the Parties on a day-to-day basis throughout the Term. Each Alliance Manager shall be permitted to attend meetings of the JSC, as appropriate and as non-voting participants. The Alliance Managers shall be the primary contact for the Parties regarding the activities contemplated by this Agreement and shall facilitate all such activities hereunder. Each Party may replace its Alliance Manager with an alternative representative at any time with prior written notice to the other Party. Any Alliance Manager may designate a substitute to temporarily perform the functions of that Alliance Manager. Each Party shall bear its own costs of its Alliance Manager.

3.7 Supply Contacts. Each Party shall designate one (1) qualified and experienced supply chain professional to serve as that Party's primary supply contact regarding the supply of the Product under this Agreement ("**Supply Contacts**"). Provided, however, if the Supply Contact who is responsible for the supply of Product and its placebo (if applicable) for Development and for Commercial use are different, each Party shall designate one (1) additional Supply Contact, if applicable. Each Party may replace a Supply Contact with an alternative representative at any time with prior written notice to the other Party. The Supply Contacts shall be responsible for facilitating information exchange and discussion between the Parties regarding the supply of the Product and its placebo (if applicable) needed for the Development of the Product in the Kissei Territory under this Agreement. ** Each Party shall bear its own costs of its Supply Contact.

4. DEVELOPMENT

4.1 Products and Companion Diagnostic.

4.1.1 Development by Kissei in Kissei Territory. Subject to the terms and conditions of this Agreement, Kissei shall have the exclusive right to Develop the Product in the Field in the Kissei Territory **, including all Development activities conducted by or on behalf of Kissei to obtain and maintain Regulatory Approval of the Product in the Kissei Territory; provided, however, that such exclusive right of Kissei is subject to Rigel's retained right to Develop the Product in the Kissei Territory ** solely for the purpose of supporting obtaining Regulatory Approval and Commercializing such Products in the Rigel Territory. For clarity, such Clinical Studies include but are not limited to Clinical Studies of the Product in the Initial Indication.

4.1.2 Kissei Participation in Rigel Global Trials. In addition, Rigel will discuss with Kissei in good faith, ** potential participation by Kissei in any global Registrational Study conducted by or on behalf of Rigel for the Product, and Kissei may participate in the global Registrational Study upon Rigel's approval, which shall not be unreasonably withheld, or delayed. **.

4.1.3 Companion Diagnostic Development. Kissei shall have a right to Develop the Companion Diagnostic in the Kissei Territory, including the conduct of all Clinical Studies to obtain and maintain Regulatory Approval of the Companion Diagnostic in the Kissei Territory in cooperation with a Third Party (the "**CDx Company**"). To facilitate Kissei's Development of the Companion Diagnostic, Rigel will cooperate with the development of the Companion Diagnostic with the CDx Company that has the capability of Developing the Companion Diagnostic via the JSC, and Rigel and the CDx Company, under which the CDx Company will collaborate with Kissei to Develop the Companion Diagnostic in the Kissei Territory. **

4.2 Development Diligence.

4.2.1 General. Subject to Section 4.2.2, Kissei shall use Commercially Reasonable Efforts to Develop the Product in any and all Indications approved by the FDA now or in the future on behalf of Rigel or any of its Affiliates or sublicensees, to perform the Development activities in accordance with the Development Plan **, and to file MAAs and seek and maintain Regulatory Approval ** for the Product in any and all Indications approved by the FDA now or in the future on behalf of Rigel or any of its Affiliates or sublicensees throughout the Kissei Territory. At Kissei's reasonable request **, Rigel shall reasonably cooperate with Kissei for the conduct of Development activities of the Product the Kissei Territory and for the seeking and filing of any Regulatory Filings and MAAs in the Kissei Territory for the Product** without delay.

4.2.2 Clinical Study and Minimum Financial Contribution. Without limiting the generality of the foregoing Section 4.2.1:

(a) Kissei shall (i) ** the PMDA ** for the Product in the Initial Indication in the Kissei Territory prior to the ** of the Effective Date, and (ii) ** prior to the ** of the Effective Date, provided that each such time period may be extended as mutually agreed by the JSC, ** (provided that Kissei continues to use Commercially Reasonable Efforts **), **, delay in Rigel providing Kissei with Know-How or Data **, delay in supply from Rigel to Kissei of the Product and its placebo (if applicable) ** (the "**Permissible Delay**"). **

(b) Between the Effective Date and the ** of the Effective Date, Kissei shall spend ** in Development Costs.

(c) Within the ** following ** by or on behalf of Kissei in the Kissei Territory for the Initial Indication, Kissei shall use Commercially Reasonable Efforts ** additional Clinical Study in any Indication other than the Initial Indication**.

(d) With respect to the milestone timelines set forth in subsections 4.2.2(a) and 4.2.2(b) above, the following shall apply:

(i) If Kissei fails to ** (which deadline shall be extended by the period of any Permissible Delay), Kissei shall pay to Rigel **, which payment shall be fully creditable against the next milestone payment under Section 8.2 that becomes payable by Kissei , and if Kissei elects not to make such payment, Rigel shall have the right to terminate this Agreement pursuant to Section 13.2.1. If Kissei makes such payment but again fails to **, then Rigel will have the right to terminate this Agreement pursuant to Section 13.2.1. Notwithstanding foregoing, if **, Parties shall discuss with good faith.

(ii) If Kissei fails to achieve its obligations under the foregoing subsection (b), Kissei shall pay to Rigel **, which payment shall be creditable against any milestone payment under Section 8.2 or any other payment under this Agreement, and if Kissei elects not to make such payment, Rigel shall have the right to terminate this Agreement pursuant to Section .

4.2.3 Sublicensing Requirements. Kissei shall use Commercially Reasonable Effort to grant to a Third Party the right to Develop and Commercialize the Product in any country or region in the Kissei Territory promptly. If, by the ** of the Effective Date with respect to Korea or Taiwan, Kissei has accomplished none of the following: (i) ** for the Product in such country or region, or (ii) ** for the Product in such country or region, or (iii) ** the Product in such country or region, then Rigel shall inform Kissei of its decision to regain the right to the Product

in the applicable country or region and the Parties shall promptly, and in any event within ** after Rigel so informs Kissei, confirm in writing that such country or region shall no longer be included in the Kissei Territory under this Agreement. For clarity, if the Parties fail to so confirm in writing that any such country or region is no longer included in the Kissei Territory within such ** period, such country or region shall automatically be excluded from the Kissei Territory upon the expiration of such ** period. In addition, if, prior to Kissei's **, Rigel or Kissei receives a sublicensing request under the licenses granted to Kissei under this Agreement to Develop and Commercialize the Product in such country or region, then Kissei shall use good faith efforts to negotiate a sublicense agreement with the requesting party on commercially reasonable terms and in accordance with Section 2.1.2.

4.3 Development Plan. The Development activities anticipated to be undertaken by Kissei or its Sublicensee(s), as applicable, for the Product to achieve Regulatory Approval in the Field in the Kissei Territory shall be set forth in a development plan (each such plan, a "**Development Plan**"). Development activities set forth in each Development Plan shall at all times be designed to be in compliance with all Applicable Laws (including good scientific and clinical practices under the Applicable Laws of the country in which such activities are conducted) and in accordance with professional and ethical standards customary in the pharmaceutical industry. The initial Development Plan describing Kissei's or its Sublicensee(s)' Development activities with respect to the Product are set forth in the Development Plan attached hereto and incorporated herein by reference as **Schedule 4.3** (the "**Initial Development Plan**"). Kissei shall provide Rigel an updated Development Plan through the JSC **, including a description of the Development activities anticipated to be undertaken by Kissei, or its Sublicensee(s), as applicable. The Initial Development Plan does not describe Development activities with respect to the Companion Diagnostic in Kissei Territory, but Kissei shall be responsible for providing Rigel with the updates of Companion Diagnostic Development conducted by CDx Company through the JSC **.

4.4 Development Reports. Kissei or its Sublicensee(s), as applicable, shall provide to Rigel a written, detailed summary of the Development activities conducted and results obtained by or on behalf of Kissei, its Sublicensee(s), as applicable, or CDx Company for the Product and the Companion Diagnostic through the JSC **. Such summary shall include a high-level summary of any Development plans or activities, the work performed in relation to the goals of the applicable Development Plan, a summary of progress against each development and regulatory milestone event and an estimate of the timing of the achievement of the next development and regulatory milestone event in each case that are described in Section 8.2. Kissei or its Sublicensee(s), as applicable, shall provide such other information as may be reasonably requested by Rigel with respect to such Development activities, including relevant activities conducted and being conducted by Kissei or its Sublicensee(s), as applicable, in the applicable period. If the information requested by Rigel is regarding Companion Diagnostic Development, Kissei shall discuss with the CDx Company and use Commercially Reasonable Efforts to provide Rigel with such information In addition to the foregoing, upon Rigel's reasonable request, Kissei or its Sublicensee(s) shall participate in a telephone or video conference to discuss such summary and other information as to convey a reasonably comprehensive understanding of the status of the applicable Development activity through the JSC. In addition, after the completion of any Clinical Study or other study of the Products, Kissei shall in a timely manner provide the Rigel with a data package ** Data specified in the Development Plan or otherwise agreed in writing by the Parties. The Parties shall discuss the status, progress, and results of Kissei's Development activities under this Agreement at JSC meetings.

4.5 Records. Each Party shall maintain complete and accurate records (paper or electronic as applicable) of all Development activities conducted by or on behalf of each Party under this Agreement in connection with the Product and the Companion Diagnostic as required by Applicable Laws, which shall include all data and other information resulting from such Development activities. These records shall include, as applicable, books, records, reports, research notes, charts, graphs, comments, computations, analyses, recordings, photographs, computer programs and documentation thereof (*e.g.*, samples of materials and other graphic or written data generated in connection with such Development activities), in sufficient detail, including in sufficient detail for regulatory purposes or filing, prosecuting, or maintaining patents, in good scientific manner, or otherwise in a manner that reflects all work done and results achieved. Each Party shall document all non-clinical studies and Clinical Studies in formal written study reports according to Applicable Laws and national and international guidelines (e.g., ICH guidelines, GCP, GLP, and GMP).

4.6 Use of Subcontractors. Each Party may perform its Development activities under this Agreement through one or more subcontractors, provided that (a) each Party will remain responsible and liable for the work allocated to, and payment to, such subcontractors to the same extent it would if it had done such work itself, (b) each subcontractor undertakes in writing obligations of confidentiality and non-use regarding Confidential Information that

are substantially the same as those undertaken by the Parties pursuant to Article 12, and (c) each subcontractor agrees in writing to assign all intellectual property developed in the course of performing any such work to each Party (or, in the event such assignment is not feasible, a license to such intellectual property with the right to sublicense to each Party).

4.7 Restrictions. During the Term, neither Party nor any of its Affiliates or Sublicensees shall, directly or through any Third Party, sponsor, conduct, cause to be conducted, otherwise assist in, supply any Product for use in connection with, or otherwise fund any research or Development of any Product that is inconsistent with this Agreement. For clarity and without limiting the foregoing, if Kissei wishes to perform or sponsor any study or test on Olutasidenib or the Products, including any pre-clinical or non-clinical study, toxicology study, or CMC-related study, Kissei shall first prepare and provide to Rigel a proposal detailing such study for Rigel's approval.

4.8 Combination Product Development; ** Development.

4.8.1 If Kissei desires to Develop a Product in combination with another product, either as a Combination Product or combination therapy, then Kissei shall notify Rigel via the JSC and the JSC shall discuss such proposed Development work at its next regularly scheduled meeting.

4.8.2 For a period of ** after the Effective Date, if Kissei wishes to initiate a Clinical Study **, the Parties shall negotiate in good faith for the conduct of such Clinical Study, and such initiation shall require the consent of Rigel.

4.9 Materials Transfer. In order to facilitate the Development activities contemplated by this Agreement, either Party may provide the other Party certain biological materials or chemical compounds with their certificate of analysis, including, but not limited to Active Ingredient, excipients, packaging materials, reference standard and metabolite, Controlled by the supplying Party (collectively, "**Materials**") **. Except as otherwise provided for under this Agreement, all such Materials delivered to the other Party will remain the sole property of the supplying Party, will be used only in furtherance of the Development activities conducted in accordance with this Agreement, will not be used or delivered to or for the benefit of any Third Party, except to subcontractors, without the prior written consent of the supplying Party, and will be used in compliance with all Applicable Laws. The Materials supplied under this Agreement must be used with prudence and appropriate caution in any experimental work because not all of their characteristics may be known. Except as expressly set forth in this Agreement, THE MATERIALS ARE PROVIDED "AS IS" AND WITHOUT ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR ANY PARTICULAR PURPOSE OR ANY WARRANTY THAT THE USE OF THE MATERIALS WILL NOT INFRINGE OR VIOLATE ANY PATENT OR OTHER PROPRIETARY RIGHTS OF ANY THIRD PARTY.

5. REGULATORY MATTERS

5.1 Responsibility for Regulatory Matters.

5.1.1 Kissei shall be solely responsible, **, for all regulatory matters relating to the Product and the Companion Diagnostic in the Kissei Territory, , including (a) overseeing, monitoring and coordinating all regulatory actions, communications, commitments and filings with, and responsibilities and submissions to, the applicable Regulatory Authority with respect to the Product and the Companion Diagnostic; (b) interfacing, corresponding and meeting with the applicable Regulatory Authority with respect to the Product and the Companion Diagnostic; (c) seeking and maintaining all Regulatory Approvals and Regulatory Filings with respect to the Product and the Companion Diagnostic, including any amendments, supplements or modifications to Regulatory Approvals and Regulatory Filings; and (d) maintaining and submitting all records and reports required to be maintained or required to be submitted to the applicable Regulatory Authority with respect to the Product and the Companion Diagnostic, each as required by Applicable Laws.

5.1.2 The Development Plan shall set forth the regulatory strategy for seeking Regulatory Approval for the Product by the appropriate Regulatory Authorities in the Kissei Territory. Subject to the oversight of the JSC and except as otherwise set forth in the Development Plan, Kissei shall be responsible for implementing such regulatory strategy in the Kissei Territory. Except as otherwise provided herein or in the Development Plan or required by Applicable Laws, Kissei shall be responsible for the preparation and submission of any and all registrations and MAAs for the Product and the Companion Diagnostic (including if such registrations and MAAs or filed by the

CDx Company on Kissei's behalf) in the Kissei Territory and shall own and hold all such Regulatory Filings (including Regulatory Approvals). At Kissei's reasonable request and expense **, Rigel shall cooperate with Kissei in the preparation of any Regulatory Filings or responses to inquiries from a Regulatory Authority in the Kissei Territory, including by providing necessary Data and technical information and technical support without delay.

5.1.3 Kissei acknowledges that Rigel may be required to communicate with Regulatory Authorities in the Kissei Territory with regard to the Rigel's Development and Manufacturing activities in the Kissei Territory. Rigel shall notify Kissei as soon as reasonably possible of such communication with Regulatory Authorities in the Kissei Territory and consider any Kissei comments to such communications in good faith.

5.2 Kissei's Right of Reference.

5.2.1 Rigel hereby grants to Kissei a right of reference to all Regulatory Approvals and Regulatory Filings submitted to any Regulatory Authority in the U.S. for the Product that are by or on behalf of Rigel and Controlled by Rigel for Kissei and its designees to exercise its rights and satisfy its obligations under this Agreement. Kissei may use such right of reference to seek, obtain, and maintain Regulatory Approval of the Product in the Kissei Territory. For the purposes of this Agreement, "right of reference" means the "right of reference or use" as defined in 21 C.F.R. §314.3(b) and any equivalent regulation outside the U.S., as each may be amended. Rigel shall provide appropriate notification of Kissei's access and right of reference to the applicable Regulatory Authorities, at Kissei's expense.

5.3 Rigel's Right of Reference.

5.3.1 Kissei hereby grants to Rigel a right of reference to all Regulatory Approvals and Regulatory Filings submitted to any Regulatory Authority in the Kissei Territory for the Product and, to the extent permitted under the agreement between Kissei and the applicable CDx Company, for the Companion Diagnostic. Kissei shall use Commercially Reasonable Efforts to obtain all rights from the CDx Company necessary for Rigel to receive the right of reference described in this Section 5.3.1 with respect to the Companion Diagnostic. Kissei shall notify Rigel in writing promptly after securing such right of reference for the Companion Diagnostic from such CDx Company. Rigel may use such Companion Diagnostic Right of Reference to seek, obtain, and maintain Regulatory Approval of the Product in the Rigel Territory. Kissei shall provide appropriate notification of Rigel's access and right of reference to the applicable Regulatory Authorities, at Rigel's expense.

5.3.2 Kissei shall, in a timely manner, provide Rigel with copies of the final version and at least one (1) interim draft version of any Regulatory Filings for Rigel's review, prepared, submitted, or received by Kissei in the Kissei Territory pertaining to the Product, and Rigel shall have the right to review and comment on such Regulatory Filings. Kissei shall share with Rigel the following communications/correspondence with any Regulatory Authority: (a) summary of contact reports Kissei receives concerning substantive conversations or substantive meetings in the Kissei Territory with the PMDA with respect to the Product or if contacts with those Regulatory Authorities are made orally, to be reduced in writing, (b) documents related to regulatory milestones and dates (e.g., submission, validations, agency review questions, and opinions, and their equivalent), and (c) cover letters of all agency submissions relating to the Product. For clarity, in each case (a)-(c), the documents shared with Rigel shall be provided "as is" and, to the extent available, Kissei shall provide an English translation to Rigel (machine translation shall be allowed). Kissei shall use Commercially Reasonable Efforts to grant to Rigel access and rights to use any such communications with any Regulatory Authority generated by or on behalf of any Sublicensee. Should Kissei fail to obtain such access and rights from any Sublicensee, Kissei shall not have the right to grant access or rights to such Sublicensee to any Regulatory Filing or right of reference granted to Kissei by Rigel pursuant to Section 5.2.1.

5.3.3 To the extent received from the CDx Company, Kissei shall , in a timely manner, provide Rigel with copies of the final version and at least one (1) interim draft version of any Regulatory Filings for Rigel's review, prepared, submitted, or received by Kissei in the Kissei Territory pertaining to the Companion Diagnostic, and, to the extent Kissei has the right to review and comment on such Regulatory Filings under the CDx Company Agreement, Rigel shall have the right to review and comment on such Regulatory Filings. To the extent Kissei has the right to do so under the terms of the CDx Company Agreement, Kissei shall share with Rigel the following communications/correspondence with any Regulatory Authority: (a) summary of contact reports Kissei receives concerning substantive conversations or substantive meetings in the Kissei Territory with the PMDA with respect to the Companion Diagnostic or if contacts with those Regulatory Authorities are made orally, to be reduced in writing, (b) documents related to regulatory milestones and dates (e.g., submission, validations, agency review questions, and

opinions, and their equivalent), and (c) cover letters of all agency submissions relating to the Companion Diagnostic. For clarity, in each case (a)-(c), the documents shared with Rigel shall be provided "as is" and, to the extent available, Kissei shall provide an English translation to Rigel (machine translation shall be allowed). Kissei shall use Commercially Reasonable Efforts to grant to Rigel access and rights to use any such communications with any Regulatory Authority generated by or on behalf of any Sublicensee.

5.4 Meetings with Regulatory Authorities. On a current and ongoing basis, Kissei shall provide Rigel with a list and schedule of any in-person meeting or material teleconference with the Regulatory Authorities (or related advisory committees) in the Kissei Territory planned for the next Calendar Quarter that relates to the Development of the Product and the Companion Diagnostic under the Development Plan in the Kissei Territory (each, a "**Regulatory Meeting**"). In addition, Kissei shall notify Rigel as soon as reasonably possible if Kissei becomes aware of any additional Regulatory Meetings that become scheduled for such Calendar Quarter and will keep Rigel informed of any significant interface or communication with any Regulatory Authority which might affect efforts to obtain Regulatory Approval for the Product in the Kissei Territory. Kissei shall be solely responsible for any communications with any Regulatory Authorities occurring or required in connection with performing its regulatory responsibilities set forth in this Article 5 with respect to the Product and the Companion Diagnostic in the Kissei Territory, and Rigel shall have the right to provide input in preparation for all such Regulatory Meetings and Rigel may have its representatives attend any such Regulatory Meetings at Rigel's expense. To the extent necessary for Rigel to exercise its rights under this Section 5.4, Kissei shall use Commercially Reasonable Efforts to cause the CDx Company to perform Kissei's obligations under this Section 5.4.

5.5 Regulatory Inspections. Each Party shall permit the Regulatory Authorities to conduct inspections of itself, its Affiliates, its licensees and its Sublicensees and subcontractors (including Clinical Study sites) relating to the Development of the Product under the Development Plan, and shall ensure that such Affiliates, its licensees and its Sublicensees and subcontractors permit such inspections. In addition, each Party shall promptly notify the other Party of any such inspection and shall supply the other Party with all information pertinent thereto. Each Party shall have the right to have a representative attend any such inspection at the attendee's Party's expense.

5.6 Adverse Event Reporting; Pharmacovigilance Agreement. As soon as reasonably practicable after the Effective Date, the Parties shall enter into a pharmacovigilance agreement setting forth the worldwide pharmacovigilance procedures for the Parties with respect to the Product, such as Safety Data sharing, adverse events reporting, and safety signal and risk management (the "**Pharmacovigilance Agreement**"), which agreement shall be amended by the Parties ** to comply with any changes in Applicable Laws or any guidance received from Regulatory Authorities. Such procedures shall be in accordance with, and enable the Parties to fulfill, local and national regulatory reporting obligations under Applicable Laws (including, to the extent applicable, those obligations contained in ICH guidelines) to monitor patients' safety. Rigel has established, and shall continue to hold (either by itself or through a vendor engaged by Rigel) the global safety database for the Product, and shall maintain such global safety database for so long as such Product is under Development or Commercialization by the Parties. The Parties will collaboratively agree on data cut points for periodic aggregate safety reports and Rigel will author such reports; the Parties will jointly review and approve such reports before submission to worldwide Regulatory Authorities as required. Rigel shall ** such database and preparing such reports. Kissei shall maintain its own safety database for the Product in the Kissei Territory and shall provide all Safety Data, including adverse event reports, in such database to Rigel in accordance with this Section 5.6 and the Pharmacovigilance Agreement. Kissei shall ** such database for the Kissei Territory and preparing reports in the Kissei Territory. Rigel will ensure that each Party is able to access the data from the global safety database in order to meet legal and regulatory obligations. The JSC shall establish a safety subcommittee, and all Safety Data, including adverse event reports, shall be submitted to such safety subcommittee and Rigel concurrently so that Rigel may update the global safety database accordingly. Such safety subcommittee shall coordinate with respect to any Safety Data reporting for the Product to the Regulatory Authorities in the Kissei Territory, but each Party shall be primarily responsible for reporting quality complaints, adverse events, and Safety Data related to the Product to any necessary Regulatory Authorities, and responding to safety issues and to all requests of Regulatory Authorities related to the Product under any MAA or Regulatory Approval for the Product held by such Party and filed with such Regulatory Authorities**. Each Party agrees to comply with its respective obligations under the Pharmacovigilance Agreement and to cause its Affiliates, licensees, and sublicensees to comply with such obligations.

5.7 No Harmful Actions. If a Party reasonably believes that the other Party is taking or intends to take any action with respect to a Product that could reasonably be expected to have a material adverse impact upon the

regulatory status of such Product in the first Party's territory, then such Party may bring the matter to the attention of the JSC and the Parties shall discuss in good faith to promptly resolve such concern.

5.8 Notification of Threatened Action. Each Party shall notify the other Party within **, after receiving any information regarding any threatened or pending action, inspection, or communication by any Regulatory Authority which may adversely affect the safety or efficacy claims of any Product or the continued Development or Commercialization of any Product. Upon receipt of such information, the Parties shall promptly consult with each other in an effort to arrive at a mutually acceptable procedure for taking appropriate action.

5.9 Recalls. In the event that a recall, withdrawal, or correction (including the dissemination of relevant information) of any Product in a Party's territory is required by a Regulatory Authority of competent jurisdiction, or if any Regulatory Authority requires or advises either Party or such Party's Affiliates or sublicensees to distribute a "Dear Doctor" letter or its equivalent regarding use of such Product in a Party's territory, or if a recall, withdraw, or correction of a Product in its territory is deemed advisable by such Party in its sole discretion, such Party shall so notify the other Party no later than ** in advance of the earlier of (a) initiation of a recall, withdrawal, or correction, or (b) the submission of plans for such an action to a Regulatory Authority. Any such recall, withdrawal, correction, or dissemination of information (e.g., "Dear Doctor" letter) shall be referred to herein as a "**Recall**". Promptly after being notified of a Recall, each Party shall provide the other Party with such assistance in connection with such Recall as may be reasonably requested by such other Party. All costs and expenses in connection with a Recall ** shall be paid by **, including the costs and expenses related to the dissemination of relevant information. Each Party shall handle exclusively the organization and implementation of all Recalls of the Products in its territory. Notwithstanding the foregoing, any Recall related to the manufacture and supply of the Product by Rigel to Kissei shall be governed by the terms and conditions of the Supply Agreement.

5.10 Sunshine Reporting Laws. Each Party acknowledges that the other Party may be subject to federal, state, local, and international laws, regulations, and rules related to the tracking and reporting of payments and transfers of value provided to health care professionals, health care organizations, and other relevant individuals and entities (collectively, "**Sunshine Reporting Laws**"), and agrees to provide the other Party with all information regarding such payments or transfers of value pertaining to the Joint Development Work by such Party in the form separately agreed in advance by the Parties as necessary for such other Party to comply in a timely manner with its reporting obligations under the Sunshine Reporting Laws.

6. COMMERCIALIZATION

6.1 General. Subject to the terms and conditions of this Article 6, Kissei shall have the sole and exclusive responsibility, at its own expense, for all aspects of the Commercialization of the Product in the Kissei Territory, including (a) developing and executing a commercial launch and pre-launch plan, (b) negotiating with applicable Governmental Authorities and other payors regarding the price and reimbursement status of the Product, (c) marketing and promotion, (d) booking sales and distribution and performance of related services, (e) handling all aspects of order processing, invoicing and collection, inventory and receivables, (f) providing customer support, including handling medical queries, and performing other related functions, and (g) conforming its practices and procedures to Applicable Laws relating to the promotion, sales and marketing, access, and distribution of the Product in the Kissei Territory.

6.2 Commercialization Plan. As soon as reasonably practicable, but no later than **, Kissei shall prepare and present to the JSC a reasonably detailed plan for the Commercialization of the Product in the Kissei Territory (the "**Commercialization Plan**"). The Commercialization Plan shall include such information on a country-by-country basis, as applicable. Kissei shall update and amend the Commercialization Plan on ** basis following the First Commercial Sale of the Product in the Kissei Territory and present such updates and any amendments to the JSC for review and discussion. Subject to the provisions of this Agreement and compliance with the Commercialization Plan, Kissei shall have full Control and authority with respect to the day-to-day Commercialization of the Product and implementation of the Commercialization Plan.

6.3 Diligence.

6.3.1 General. During the Term, Kissei shall use Commercially Reasonable Efforts to Commercialize the Product for each and every Indication that has received or will receive Regulatory Approval in the Kissei Territory.

6.3.2 Product Launch. Kissei shall launch the Product for each Indication that has received Regulatory Approval in the Kissei Territory as soon as reasonably possible following receipt of such Regulatory Approval. As applicable, Kissei shall obtain all Pricing and Reimbursement Approvals necessary to launch such Product for such Indication as soon as reasonably possible following receipt of MAA Approval of such Product in a country. Without limiting the generality of the foregoing, Kissei shall launch the Product in each country in the Kissei Territory within ** after receiving Regulatory Approval (or, where applicable, Pricing and Reimbursement Approval) of the Product for an Indication from the applicable Regulatory Authority in such country. Thereafter, Kissei shall utilize Commercially Reasonable Efforts in the ongoing support for the Product in each country in the Kissei Territory.

6.3.3 Commercial Financial Contribution. Kissei shall spend ** in connection with the marketing and promotion of the Product in the Kissei Territory.

6.3.4 Minimum Sales Force. During the Term, Kissei shall engage in-house sales representatives to promote and detail the Product in Japan. Without limiting the generality of the foregoing, prior to the date that is **, Kissei shall have engaged ** in-house sales representatives to promote and detail the Product in Japan.

6.3.5 Reporting Obligations. Kissei shall update the JSC on ** basis regarding its Commercialization activities with respect to the Products in the Kissei Territory. Each such update shall be in a form to be agreed by the JSC and shall summarize Kissei's and its Affiliates' and Sublicensees' significant Commercialization activities, and shall contain at least such information at such level of detail reasonably required by Rigel to determine Kissei's compliance with its diligence obligations set forth in this Section 6.3. Such updates shall include Kissei's sales activities, sales forecasts for at least the next **, marketing activities, and Medical Affairs. In addition, Kissei shall provide Rigel with written notice of the commercial launch of the Product (i.e., when the Product becomes made available to its end users) in the Kissei Territory within ** after such event. Kissei shall provide such other information as Rigel may reasonably request with respect to Commercialization of the Product.

6.4 Coordination of Commercialization Activities.

6.4.1 Generally. Kissei, through the JSC (or JCC or other designated team), shall update Rigel on Commercialization strategies for the Product (e.g., for branding and messaging, international congresses, advisory boards) in the Kissei Territory, and shall assist Rigel to identify and take advantage of any potential global strategies and messaging. The foregoing shall not be construed as requiring Kissei to seek Rigel's consent in connection with Kissei establishing or implementing any sales, marketing, or medical affairs practices in the Kissei Territory.

6.4.2 Pricing. Kissei shall keep Rigel timely informed on the status of any application for Pricing and Reimbursement Approval or material updates to an existing Pricing and Reimbursement Approval in the Kissei Territory, including any discussion with a Regulatory Authority with respect thereto. Kissei and its Affiliates and Sublicensees shall not sell any Product **, in such a manner as to ** the selling price of the Product **.

6.4.3 Sharing of Promotional Materials. Kissei shall, at its own expense, prepare, develop, produce, or otherwise obtain and utilize sales, promotional, advertising, marketing, website, educational, and training materials (the "**Promotional Materials**") to support its Commercialization activities in the Kissei Territory, and shall ensure that such Promotional Materials, as well as all information contained therein, comply with all Applicable Laws and are consistent with any Regulatory Approvals obtained for the Product in the applicable jurisdiction in the Kissei Territory. At Rigel's written reasonable request, Kissei shall share samples of and updates to Promotional Materials with respect to the Commercialization of the Product with Rigel. For clarity, the Promotional Materials shall be provided to Rigel "as is".

6.5 Coordination of Global Medical Affairs. Rigel shall be responsible for all Medical Affairs for the Product in the Rigel Territory, and Kissei shall be responsible for Medical Affairs in the Kissei Territory; provided, however, that Rigel shall have the right, but not the obligation, to also conduct Medical Affairs in the Kissei Territory in global support of the Product under prior approval of the JSC. Kissei will not undertake Medical Affairs in the Rigel Territory without Rigel's prior written consent to be given on a case-by-case basis.

6.6 Diversion. Each Party hereby covenants and agrees that it and its Affiliates shall not, and it shall contractually obligate (and use Commercially Reasonable Efforts to enforce such contractual obligation) its sublicensees not to, directly or indirectly, promote, market, distribute, import, sell, or have sold any Product, including via the Internet or mail order, to any Third Party or to any address or Internet Protocol address or the like in the other

Party's territory. Neither Party shall engage, nor permit its Affiliates and sublicensees to engage, in any advertising or promotional activities relating to any Product for use directed primarily to customers or other buyers or users of such Product located in any country or jurisdiction in the other Party's territory, or solicit orders from any prospective purchaser located in any country or jurisdiction in the other Party's territory. If a Party or its Affiliates or sublicensees receives any order for a Product for use from a prospective purchaser located in a country or jurisdiction in the other Party's territory, such Party shall immediately refer that order to such other Party and shall not accept any such orders. Neither Party shall, nor permit its Affiliates and sublicensees to, deliver or tender (or cause to be delivered or tendered) any Product for use in the other Party's territory.

7. MANUFACTURE AND SUPPLY

7.1 Rigel shall manufacture and supply, itself or through a Third Party contract manufacturer the Product and its placebo (if applicable) as the exclusive manufacturer and supplier of Kissei. Product shall be supplied as commercial Product in the Rigel Territory, in mutually agreed upon form (such as brite stock in naked bottles or bulk capsules), without final packaging, serialization or labeling, for use in the Development and Commercialization of the Product under this Agreement. Product shall meet quality approved regulatory specifications in Kissei Territory and quality and quantities for a demand of Kissei Territory.

7.1.1 All Product and its placebo (if applicable) supplied by Rigel to Kissei for use for Development purposes shall be ** such Product **. ** Kissei shall provide Rigel with each request for the Product for Development purposes ** of the Product ordered **.

7.1.2 All Product supplied by Rigel to Kissei for use for Commercialization purposes shall be subject to the pricing set forth in Section 8.4. Kissei shall be responsible, at its expense, for the final packaging , serialization and labeling of the Product for all countries in the Kissei Territory. Kissei shall also be responsible, at its sole expense, for any specific manufacturing activities required or useful in the Kissei Territory, such as stability studies or development of finished product presentations necessary to obtain MAA Approval of the Product in the Kissei Territory, and Rigel shall use Commercially Reasonable Effort to support such activities. **

7.2 Drug Master File. In connection with Kissei's preparation and filing of an MAA for the Product in the Kissei Territory and to the extent required for MAA approval in the Kissei Territory, Kissei shall have a right, but not an obligation, to request Rigel to obtain and maintain a DMF, which includes the Active Ingredient and other related information of the Product, to support such filing **. Rigel shall use Commercially Reasonable Effort to obtain and maintain a DMF upon such request. If Kissei does not request or Rigel rejects Kissei's request to obtain and maintain a DMF, and Kissei manages information related to Product and Active Ingredient of Product in other ways, including, but not limited to a part of NDA filing documents in the Kissei Territory, then Rigel shall; (a) promptly provide Kissei with information required by Applicable Law that is Controlled by Rigel, including, but not limited to, the data generated by Rigel's contract manufacturers and/or contract venders to conduct related studies, (b) use Commercially Reasonable Effort to support Kissei's correspondence to Regulatory Authorities in the Kissei Territory within appropriate time by reviewing the documents, providing with required Know-How and/or Data, and supporting the communication with contract manufacture and vendors. Notwithstanding the foregoing, to the extent permissible under Rigel's agreements with its applicable contract manufacturers and vendors, Rigel shall; (A) grant Kissei a right for inspection to contract manufactures, contract venders to conduct related studies and/or storage sites, and, (B) notify Kissei all the changes related to the Product and Active Ingredient of Product in advance insofar as possible, including, but not limited to, the changes in contract manufacturers, contract venders to conduct related studies or storage sites.

7.3 Supply Agreement and Quality Agreement. Concurrently with the execution of this Agreement, the Parties shall enter into a supply agreement for the manufacture and supply of the Product to Kissei (the "**Supply Agreement**"). As soon as reasonably practicable after the execution of this Agreement, the Parties shall agree to the terms and conditions of a quality agreement for the terms and conditions related to quality of the Product (the "**Quality Agreement**").

8. FINANCIAL PROVISIONS

8.1 Upfront Payment. Kissei shall make a one-time, non-refundable, non-creditable upfront payment to Rigel of ten million dollars ($10,000,000) within ** after the Effective Date.

8.2 Development Milestone Payments.

8.2.1 Development Milestones. Subject to the remainder of this Section 8.2 and Section 8.5, Kissei shall pay to Rigel the non-refundable, non-creditable payments set forth in the table below upon the achievement of the applicable milestone event (whether by or on behalf of Kissei or its Affiliates or Sublicensees).

**** Milestones**	**Milestone Payment**
**	$**
**	$**
****Milestones**	**Milestone Payment**
**	$**
**	$**
****Milestones**	**Milestone Payment**
**	$**
**	$**
****Milestones**	**Milestone Payment**
**	$**
**	$**

For clarity, each milestone payment above shall be paid not more than once for each Indication, and the total amount payable by Kissei to Rigel pursuant to this Section 8.2.1 is **.

8.2.2 Notice and Payment. Kissei shall notify Rigel in writing within ** after the achievement of any milestone set forth in this Section 8.2 by Kissei or its Affiliates or Sublicensees. Promptly following receipt of any such notice from Kissei, Rigel will issue an invoice for the applicable development milestone payment to Kissei. Kissei shall pay to Rigel the applicable development milestone payment within ** after the receipt of such invoice.

8.3 Sales Milestones Payments.

8.3.1 Subject to Section 8.5, Kissei shall pay to Rigel the one-time, non-refundable, non-creditable payments set forth in the table below when the aggregated Net Sales of all Products ** in any Calendar Year first reach the values indicated in the table below. For clarity, subject to Section 8.5, each payment in this Section 8.3 shall be payable once only upon first achievement of the applicable milestone event, regardless of the number of times such milestone is subsequently achieved.

Aggregate Net Sales of all Products ** in a Calendar Year	**Milestone Payment**
Equal or exceed $**	$**
Equal or exceed $**	$**
Equal or exceed $**	$**
Equal or exceed $**	$**
Equal or exceed $**	$**

8.3.1 Notice and Payment. As part of the report in Section 8.7, Kissei shall provide written notice to Rigel if the aggregated Net Sales of all Products ** in any Calendar Year first reach the values set forth in Section 8.3.1 above, and Kissei shall pay to Rigel the corresponding Net Sales milestone payment within ** after the end of such Calendar Year.

8.4 Transfer Price.

8.4.1 Transfer Price.

(a) In consideration for the quantity in units of Product provided by Rigel to Kissei for Commercial use ("**Units Provided**"), Kissei shall pay to Rigel a transfer price equal to the Units Provided ** (the

"**Transfer Price**"). For clarity, the Parties will agree upon the ** for the initial order prior to the initial Purchase Order, and thereafter the Parties agree to review **. **. Additionally, Kissei shall pay to Rigel an amount to be calculated in accordance with the table below by multiplying the respective percentage rates set forth therein (the "**Transfer Price Rate**") less the Transfer Price for all Product sold by Kissei or on behalf of Kissei or its Affiliates or Sublicensees during the Commercialization Term ("**True Up Transfer Price** "). The Transfer Price amount shall be paid within ** after the ** in which Kissei receives Rigel's invoice for such Units Provided. The True Up Transfer Price amount shall be calculated and paid in accordance with Section 8.4.2 below.

Annual Net Sales of all Products **	**Transfer Price Rate**
Portion less than or equal to $**	**%
Portion greater than $** and less than or equal to $**	**%
Portion greater than $**	**%
Annual Net Sales of all Products in **	**Transfer Price Rate**
Regardless of the sales scale	**%

(b) Notwithstanding the foregoing, on a country-by-country or region-by-region basis, if ** a unit of the Product exceeds an amount equal to ** for such Units Provided in such country or region (the "**Base Percent**"), the Transfer Price Rate set forth in Section 8.4.1(a) for such Units Provided in such country or region shall be adjusted accordingly: for ** the Base Percent, the Transfer Price Rate set forth in Section 8.4.1(a) shall be increased by **, provided, however, that in no event shall the Transfer Price Rate exceed **.

(i) By way of one example only, ** for the Product equals ** of the Net Sales for such Product **, the Transfer Price Rate for such Product in such country shall be equal to ** for portions of Net Sales less than or equal to ** for portions of Net Sales greater than **, but less than **, and ** for portions of Net Sales greater than **.

(ii) By way of another example only, if ** for the Product equals ** of the Net Sales for such Product **, the Transfer Price Rate for such Product ** shall be equal to **regardless of the sales scale.

(c) The Transfer Price Rate in this Section 8.4.1 shall apply to the units of the Products sold for the period during which such Transfer Price Rate(s) applies. If the Transfer Price for the Product ** for such Product falls below an amount equal to ** for such Product, the Parties shall discuss in good faith a modification in the Transfer Price Rate(s) for such Product **.

8.4.2 True Up Transfer Price Payments During the Commercialization Term.

(a) ANS Calculation. Within ** after the end of each Calendar Quarter, Kissei shall calculate and report to Rigel in writing an estimate of the average per unit Net Sales for the Product in such Calendar Quarter, and within ** after the end of each Calendar Quarter, Kissei shall calculate and report to Rigel in writing the actual average per unit Net Sales for the Product in such Calendar Quarter (the "**ANS**") **. For ** (i) Kissei shall provide an estimate of ANS within ** after the end of each Calendar Quarter, and (ii) Kissei shall use Commercially Reasonable Effort to calculate and report to Rigel in writing the ANS in such Calendar Quarter within ** after the end of each Calendar Quarter but in no event later than ** after the end of each Calendar Quarter. The ANS shall be calculated by dividing the Net Sales for such Calendar Quarter in a country by the number of units of the Product sold by Kissei that constitutes the Net Sales for such period in such country.

(b) True Up Calculation for Units Sold. Within ** after the end of each Calendar Quarter, Kissei shall calculate and report to Rigel in writing the estimated number of units sold of Units Provided, and within ** after the end of each Calendar Quarter, Kissei shall calculate and report to Rigel in writing the actual number of units sold of Units Provided in such Calendar Quarter (the "**Units Sold**") **. For ** (i) Kissei shall provide an estimate of Units Sold within ** after the end of each Calendar Quarter, and (ii) Kissei shall use Commercially Reasonable Effort to calculate and report to Rigel in writing the Units Sold within ** after the end of each Calendar Quarter but in no event later than ** after the end of each Calendar Quarter. The true up calculation for Units Sold (the "**True Up on Units Sold**") shall be as follows: the ANS multiplied by the Transfer Price Rate less the **, which

will all be multiplied by the Units Sold [((ANS) x (Transfer Price Rate) – (**)) x (Units Sold) = True Up on Units Sold]. For clarity, the ** is calculated by **.

(c) True Up Calculation for Units Lost. Within **after the end of each Calendar Quarter, Kissei shall calculate and report to Rigel in writing the estimated number of units of Units Provided not sold, and within ** after the end of each Calendar Quarter, Kissei shall calculate and report to Rigel in writing the actual number of units of Units Provided not sold due to an identified loss in such Calendar Quarter (the "**Units Lost**") **. For ** (i) Kissei shall provide an estimate of Units Lost within ** after the end of each Calendar Quarter, and (ii) Kissei shall use Commercially Reasonable Effort to calculate and report to Rigel in writing the Units Lost within ** after the end of each Calendar Quarter but in no event later than ** after the end of each Calendar Quarter. The true up calculation for Units Lost (the "**True Up on Units Lost**") shall be as follows: [(the number of Units Lost) x (Transfer Price Per Unit - Cost of Goods Per Unit) = True Up on Units Lost]. The Parties agree that the units of Product with ** shall constitute Units Lost **.

(d) True Up Transfer Price Payment. The True Up Transfer Price payment amount will be calculated by [(True Up on Units Sold) – (True Up on Units Lost) = True Up Transfer Price payment]. If the amount of the True Up Transfer Price is a positive value, then Kissei will pay Rigel such amount within ** after Kissei receives Rigel's invoice. If the amount of the True Up Transfer Price is a negative value, then Rigel will credit Kissei such amount against future payments hereunder.

(e) Related Reporting. In connection with the foregoing subsections (b) and (c), within ** after the end of each Calendar Quarter, Kissei shall provide Rigel with a report that details the lot number of Units Sold and Units Lost **. Kissei also shall use Commercially Reasonable Effort to provide Rigel with a report that details the lot number of Units Sold and Units Lost ** within **after the end of each Calendar Quarter but in no event later than **. Additionally, Kissei shall promptly provide Rigel with any other reports or information reasonably requested by Rigel.

8.4.3 Transfer Price Adjustments.

(a) If one or more Generic Products to a Product is sold in any country in the Kissei Territory for such Product in such country, and such Generic Products ** during such Calendar Quarter, the Transfer Price Rates provided in Section 8.4.1 for such Product shall be reduced in such country by ** for such Calendar Quarter.

(b) If it is necessary for Kissei to obtain a license from a Third Party under any Patent in a particular country in the Kissei Territory in order to sell a Product in such country and Kissei obtains such a license, Kissei may deduct from the Transfer Price that would otherwise have been due pursuant to Section 8.4.1 with respect to Net Sales of such Product in such country in a particular Calendar Quarter an amount equal ** paid by Kissei to such Third Party pursuant to such license on account of the sale of such Product in such country during such Calendar Quarter. For clarity, **.

(c) Notwithstanding the foregoing, during any Calendar Quarter in the Commercialization Term for a Product in a country, the operation of subsection (a) and (b) above, individually or in combination, shall not reduce by more than ** the Transfer Price that would otherwise have been due under Section 8.4.1 with respect to Net Sales of such Product in such country during such Calendar Quarter. Kissei shall not be permitted to carry forward to subsequent Calendar Quarters any amounts it was not able to credit as a result of this subsection (c).

8.4.4 Transfer Price During the Extended Commercialization Term. In consideration for the Product provided by Rigel to Kissei for Commercial use, Kissei shall pay to Rigel a Transfer Price equal to ** for such Product ** for all the Product manufactured for sale by or on behalf of Kissei or its Affiliates or Sublicensees during the Extended Commercialization Term. For clarity, Kissei shall have the right to obtain other source(s) of supply for Olutasidenib and the Product and to conclude a contract with Rigel's manufacturers directly after the Commercialization Term.

8.4.5 Transfer Price Payments During the Extended Commercialization Term. The Transfer Price payable by Kissei to Rigel for each unit of the Product delivered to Kissei during the Extended Commercialization Term under Section 8.4.4 shall be due within ** after Kissei's receipt from Rigel of an invoice for such Product. For clarity, such payments shall not be subject to any offsets or reductions whatsoever, including those set forth in Section 8.4.3.

8.5 Korea and Taiwan Milestone Payments.

8.5.1 Development Milestone Payments. If Kissei intends on Developing Product in either of Taiwan or Korea (such country or region, a "**Development Activities Country**") by or on behalf of Kissei or its Affiliates, Kissei shall deliver written notice of such anticipated Development activities prior to undertaking such Development activities in such country (such notice, the "**Development Activities Notice**"). Kissei shall not have the right to undertake any Development activities for the Product prior to delivering a Development Activities Notice to Rigel. For a period of ** following delivery of such Development Activities Notice (such time period, the "**Development Milestone Negotiation Period**"), the Parties shall negotiate in good faith Development milestone events and Development milestone payments (such payments, "**Additional Development Milestone Payments**") that would be payable to Rigel with respect to such Development activities in such Development Activities Country. If the Parties do not agree upon the Additional Development Milestone Payments for the applicable Development Activities Country prior to the expiration of the applicable Development Milestone Negotiation Period, then Kissei shall not undertake any Development activities for the Product in the Development Activities Country. For the avoidance of doubt, in case that Kissei's Sublicensee undertake the Development activities in the Development Activities Country, the provision of Section 8.6 shall apply instead of this Section 8.5.1.

8.5.2 Commercial Milestone Payments. If Kissei intends on Commercializing Product in either of Taiwan or Korea (such country or region, the "**Commercial Activities Country**") by or on behalf of Kissei or its Affiliates, Kissei shall deliver written notice of such anticipated Commercialization activities prior to undertaking such Commercialization activities in such country (such notice, the "**Commercial Activities Notice**"). Kissei shall not have the right to undertake any Commercialization activities for the Product prior to delivering a Commercial Activities Notice to Rigel. For a period of ** following delivery of such Commercial Activities Notice (such time period, the "**Commercial Milestone Negotiation Period**"), the Parties shall negotiate in good faith Commercialization milestone events and Commercialization milestone payments (such payments, "**Additional Commercial Milestone Payments**") that would be payable to Rigel with respect to such Commercialization activities in such Commercial Activities Country. If the Parties do not agree upon the Additional Commercial Milestone Payments for the applicable Commercial Activities Country prior to the expiration of the applicable Commercial Milestone Negotiation Period, then Kissei shall not undertake any Commercial activities for the Product in the Commercial Activities Country. For the avoidance of doubt, in case that Kissei's Sublicensee undertake the Commercial activities in the Commercial Activities Country, the provision of Section 8.6 shall apply instead of this Section 8.5.2.

8.6 Sublicense Revenue. With respect to a Sublicense to a Sublicensee that is not an Affiliate of Kissei, Kissei shall pay or transfer to Rigel (A) ** of Sublicense Revenue that consists of ** of Kissei or its Affiliates **, (B) ** Sublicense Revenue **. **.

8.7 Reports; Payments. All Transfer Price payments due under Section 8 shall be accompanied by an accurate report setting forth, on a country-by-country basis, Net Sales of the Products by Kissei and its Affiliates and Sublicensees in the Kissei Territory in sufficient detail to permit confirmation of the accuracy of the Transfer Price payment made, including, for each country, the number of the Products sold, the gross sales and Net Sales of the Products, the type and amount of permitted deductions from gross sales to determine such Net Sales, the Transfer Price payable, the Sublicense Revenue received and the Sublicense Revenue payable, the calculation methods, the exchange rates used, any adjustments to the Transfer Price Rate in accordance with Section 8.4.3, and whether any Net Sales milestone under Section 8.3 has been achieved. Prior to the First Commercial Sale of the Product in the Kissei Territory, the Parties will agree on the form of such report.

8.8 Records; Audit. Each Party shall maintain complete and accurate records in sufficient detail in relation to this Agreement to permit the other Party to confirm the accuracy of the amount of the Cost of Goods to be reimbursed or shared, achievement of Net Sales milestones, and the amount of milestone payments, Transfer Price, Sublicense Revenue and other payments payable under this Agreement. Each Party will keep such books and records for at least ** following the Calendar Year to which they pertain. Upon reasonable prior notice, such records shall be

inspected during regular business hours at such place or places where such records are customarily kept by an independent certified public accountant (the "**Auditor**") selected by the auditing Party and reasonably acceptable to the audited Party for the sole purpose of verifying for the auditing Party the accuracy of the financial reports furnished by the audited Party pursuant to this Agreement or of any payments made, or required to be made, by or to the audited Party pursuant to this Agreement. Before beginning its audit, the Auditor shall execute an undertaking acceptable to each Party by which the Auditor agrees to keep confidential all information reviewed during the audit. Such audits may occur no more often than ** each Calendar Year and not more frequently than ** with respect to records covering any specific period of time. Each Party shall only be entitled to audit the books and records from the ** prior to the Calendar Year in which the audit request is made. Such auditor shall not disclose the audited Party's Confidential Information to the auditing Party, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by the audited Party or the amount of payments to or by the audited Party under this Agreement. In the event that the final result of the inspection reveals an undisputed underpayment or overpayment, the underpaid or overpaid amount shall be settled within ** after the Auditor's report. The auditing Party shall bear the full cost of such audit unless such audit reveals an overpayment to, or an underpayment by, the audited Party that resulted from a discrepancy in the financial report provided by the audited Party for the audited period, which underpayment or overpayment was more than ** of the amount set forth in such report, in which case the audited Party shall reimburse the auditing Party for the costs for such audit.

8.9 Exchange Rate; Manner and Place of Payment. All references to dollars and "$" herein shall refer to U.S. dollars. All payments hereunder shall be payable in U.S. dollars. When conversion of Net Sales from any currency other than U.S. dollars is required, such conversion shall be at the exchange rate equal to the conversion rate for the U.S. dollar for the currency of the country in which the applicable Net Sales were made as published by **. All payments owed under this Agreement shall be made by wire transfer in immediately available funds to a bank and account designated in writing by Rigel, unless otherwise specified in writing by Rigel.

8.10 Late Payments. In the event that any payment due under this Agreement is not paid when due in accordance with the applicable provisions of this Agreement, the payment shall accrue interest from the date due **; provided, however, that in no event shall such rate exceed the maximum legal annual interest rate. The payment of such interest shall not limit the Party entitled to receive payment from exercising any other rights it may have as a consequence of the lateness of any payment.

8.11 Blocked Payments. If, by reason of Laws in any jurisdiction in the Kissei Territory, it becomes impossible or illegal for Kissei to transfer milestone payments, royalties or other payments under this Agreement to Rigel, Kissei shall promptly notify Rigel. During any such period described above, Kissei shall deposit such payments in local currency in the relevant jurisdiction to the credit of Rigel in a recognized banking institution designated by Rigel or, if none is designated by Rigel within a period of **, in a recognized banking institution selected by Kissei and identified in a written notice given to Rigel.

8.12 Taxes.

8.12.1 Taxes on Income. Each Party shall be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly from the activities of the Parties under this Agreement.

8.12.2 Tax Cooperation. The Parties agree to cooperate with one another and use reasonable efforts to avoid or reduce tax withholding or similar obligations in respect of the milestone payments, Transfer Price payments, and other payments made by Kissei to Rigel under this Agreement. To the extent that Kissei is required by Applicable Laws to deduct and withhold taxes on any payment to Rigel, Kissei shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to Rigel an official tax certificate or other evidence of such payment sufficient to enable Rigel to claim such payment of taxes. Rigel shall provide Kissei any tax forms that may be reasonably necessary in order for Kissei to not withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty, to the extent legally able to do so. Rigel shall use reasonable efforts to provide any such tax forms to Kissei in advance of the due date. Kissei shall provide Rigel with reasonable assistance to enable the recovery, as permitted by Applicable Laws, of withholding taxes or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of Rigel. Kissei shall have the right to deduct any such tax, levy, or charge actually paid from payment due to Rigel. Each Party agrees to assist the other Party in claiming exemption from such deductions or withholdings under double taxation or similar agreement or treaty from time to time in force and in minimizing the amount required to be so withheld or deducted.

8.12.3 Taxes Resulting from Kissei's Action. If a Party takes any action of its own discretion (not required by a Regulatory Authority), including any assignment, sublicense, change of place of incorporation, or failure to comply with Applicable Laws or filing or record retention requirements, which results in a withholding or deduction obligation ("**Withholding Tax Action**"), then such Party shall pay the sum associated with such Withholding Tax Action. For clarity, if Kissei undertakes a Withholding Tax Action, then the sum payable by Kissei (in respect of which such deduction or withholding is required to be made) shall be increased to the extent necessary to ensure that Rigel receives a sum equal to the sum which it would have received had no such Withholding Tax Action occurred. Otherwise, the sum payable by Kissei (in respect of which such deduction or withholding is required to be made) shall be made to Rigel after deduction of the amount required to be so withheld or deducted. If a change in Applicable Laws results in a withholding or deduction obligation absent either Party taking a Withholding Tax Action, then the amount of such withholding or deduction obligation shall be paid by Kissei to the applicable Governmental Authority on behalf of Rigel, provided that Kissei shall use reasonable efforts to assist Rigel in minimizing or recovering such withholding or deduction obligation. The Parties shall use commercially reasonable efforts to invoke the application of any applicable bilateral income tax treaty that would reduce or eliminate otherwise applicable taxes with respect to payments payable pursuant to this Agreement.

8.13 Payment of Back Royalties. If Kissei would owe a royalty payment to Rigel under this Section 8.13 but for a decision by a court or other governmental agency of competent jurisdiction holding a patent claim unenforceable, unpatentable or invalid and if such decision is later vacated or reversed by a final nonappealable decision by a court or other governmental agency of competent jurisdiction such that such claim qualifies as a Valid Claim that Covers the Product in the Kissei Territory, Rigel may invoice Kissei for such unpaid royalty payments after such decision is vacated or reversed and Kissei shall make any such unpaid royalty payments to Rigel within ** after receipt of such invoice, provided Kissei shall have the right to deduct any and all costs and expenses incurred by Kissei in connection with defending such Valid Claim.

9. INTELLECTUAL PROPERTY

9.1 Ownership.

9.1.1 Data. All Data generated in connection with any Development or Commercialization activities with respect to any Product conducted solely by or on behalf of Rigel and its Affiliates and licensees (other than Kissei) (the "**Rigel Data**") shall be the sole and exclusive property of Rigel or its Affiliates or licensees, as applicable. All Data generated in connection with any Development or Commercial activities with respect to any Product conducted solely by or on behalf of Kissei or its Affiliates or Sublicensees (the "**Kissei Data**") shall be the sole and exclusive property of Kissei or of its Affiliates or Sublicensees, as applicable. For clarity, each Party shall have access and right to use and reference the other Party's Data as and to the extent set forth in this Agreement.

9.1.2 Inventions. Inventorship of any Inventions will be determined in accordance with the standards of inventorship and conception under U.S. patent laws. The Parties will work together to resolve any issues regarding inventorship or ownership of Inventions. Ownership of Inventions will be allocated as follows:

(a) Subject to Section 9.1.2(b), (i) each Party shall solely own any Inventions made solely by its and its Affiliates' employees, agents, or independent contractors, and (ii) the Parties shall jointly own any Inventions that are made jointly by employees, agents, or independent contractors of one Party and its Affiliates together with employees, agents, or independent contractors of the other Party and its Affiliates ("**Joint Inventions**"), in each case of (i) and (ii) solely to the extent such Inventions are not Compound Inventions. All Patents claiming, disclosing or covering Joint Inventions, solely to the extent such Patent are not Compound Patents, shall be referred to herein as "**Joint Patents**". Except to the extent either Party is restricted by the licenses granted to the other Party under this Agreement, each Party shall be entitled to practice, license, assign, and otherwise exploit its interest under the Joint Inventions and Joint Patents without the duty of accounting or seeking consent from the other Party.

(b) Rigel shall solely own (i) any Inventions that relate to (a) Olutasidenib or its composition, manufacture, derivatives or its use, including diagnostic inventions, or (b) any improvement of any such composition, manufacture, or use of Olutasidenib, including in combination with other agents or components, regardless whether such Inventions are made solely by one Party and its Affiliates' employees, agents, or independent contractors, or jointly by employees, agents, or independent contractors of one Party and its Affiliates together with employees, agents, or independent contractors of the other Party and its Affiliates ("**Compound Inventions**"), and (ii) all intellectual property rights in the Compound Inventions, including all Patents claiming, disclosing or covering

Compound Inventions ("**Compound Patents**"). To the extent that any Compound Invention is made by Kissei and its Affiliates' employees, agents, or independent contractors, whether solely or jointly with Rigel and its Affiliates' employees, agents, or independent contractors, such Compound Invention shall be included in the license granted to Kissei by Rigel under Section 2.1, provided, however, that, in such cases it shall be excluded the Valid Claim, without additional consideration. Without any additional consideration, Kissei agrees to assign and hereby assigns to Rigel its rights, title, and interest in and to all Compound Inventions and Compound Patents.

9.2 Patent Prosecution and Maintenance.

9.2.1 Rigel Patents.

(a) Subject to this Section 9.2.1, Rigel shall have the sole right and obligation (subject to Section 9.2.1(b)) to control the preparation, filing, prosecution, and maintenance (including any interferences, reissue proceedings, reexaminations, inter partes review, patent term extensions, applications for supplementary protection certificates, oppositions, invalidation proceedings and defense of validity or enforceability challenges) of the Rigel Patents and Joint Patents worldwide, ** and using counsel of its own choice. Rigel shall keep Kissei informed of material progress with regard to the preparation, filing, prosecution, and maintenance of the Rigel Patents in the Kissei Territory, sufficiently in advance for Kissei to be able to review any material documents, including content, timing, and jurisdiction of the filing of such Rigel Patents in the Kissei Territory, and Rigel shall consult with, and consider in good faith the requests and suggestions of, Kissei with respect to strategies for filing, prosecuting, and defending, if any, the Rigel Patents in the Kissei Territory.

(b) In the event that Rigel desires to abandon or cease prosecution or maintenance of any Rigel Patent or Joint Patent in any country in the Kissei Territory, Rigel shall provide reasonable prior written notice to Kissei of such intention to abandon (which notice shall, to the extent possible, be given no later than ** prior to the next deadline for any action that must be taken with respect to any such Rigel Patent or Joint Patent in the relevant patent office). In such case, upon Kissei's written election provided no later than ** after such notice from Rigel, Kissei shall have the right to assume prosecution and maintenance of such Rigel Patent or Joint Patent at Kissei's expense, and any claim included in such Rigel Patent or Joint Patent shall cease to be a Valid Claim under this Agreement. If Kissei does not provide such election within ** after such notice from Rigel, Rigel may, in its sole discretion, continue prosecution and maintenance of such Rigel Patent or Joint Patent or discontinue prosecution and maintenance of such Rigel Patent or Joint Patent.

(c) Rigel shall update **Schedule 10.3.1** on ** basis during the Commercialization Term. Notwithstanding the foregoing, solely with respect to ** during the Term, Kissei shall have the right to ** the update **. If Rigel ** but shall also ** under this Agreement, provided that, for clarity, in the event ** under this Agreement. If Rigel disagrees with Kissei **, such disagreement shall be subject to the dispute resolution process set forth in Article 14.

9.2.2 Kissei Patents.

(a) Subject to this Section 9.2.2, Kissei shall have the first right, but not the obligation, to control the preparation, filing, prosecution and maintenance (including any interferences, reissue proceedings, reexaminations, patent term extensions, applications for supplementary protection certificates, oppositions, invalidation proceedings, and defense of validity or enforceability challenges) of all Kissei Patents worldwide, ** by counsel of its own choice in the Kissei Territory and by counsel mutually agreed to by the Parties in the Rigel Territory. Kissei shall keep Rigel informed of the status of filing, prosecution, maintenance, and defense, if any, of the Kissei Patents, and, ** Patents claiming or covering a Compound Invention, Kissei shall consult with, and consider in full good faith the requests and suggestions of Rigel with respect to strategies for filing, prosecuting, and defending such Kissei Patents.

(b) In the event that Kissei desires to abandon or cease prosecution or maintenance of any Kissei Patent, Kissei shall provide reasonable prior written notice to Rigel of such intention to abandon (which notice shall, to the extent possible, be given no later than ** prior to the next deadline for any action that must be taken with respect to any such Kissei Patent in the relevant patent office). In such case, upon Rigel's written election provided no later than ** after such notice from Kissei, Rigel shall have the right to assume prosecution and maintenance of such Kissei Patent at Rigel's expense and Kissei shall assign to Rigel all of its rights, title, and interest in and to such Kissei Patent. If Rigel does not provide such election within ** after such notice from Kissei, Kissei

may, in its sole discretion, continue prosecution and maintenance of such Kissei Patent or discontinue prosecution and maintenance of such Kissei Patent.

9.2.3 Cooperation. Each Party agrees to cooperate fully in the preparation, filing, prosecution, maintenance, and defense, if any, of Patents under Section 9.2 and in the obtaining and maintenance of any patent term extensions and supplementary protection certificates and their equivalents, **. Such cooperation includes (i) executing all papers and instruments, or requiring its employees or contractors, to execute such papers and instruments, so as enable the other Party to apply for and to prosecute patent applications in any country as permitted by Section 9.2; and (ii) promptly informing the other Party of any matters coming to such Party's attention that may affect the preparation, filing, prosecution, or maintenance of any such patent application and the obtaining of any patent term extensions or supplementary protection certificates or their equivalents.

9.3 Patent Enforcement.

9.3.1 Notice. Each Party shall notify the other within ** of becoming aware of any alleged or threatened infringement by a Third Party of any of the Rigel Patents and Joint Patents in the Kissei Territory, which infringement adversely affects or is reasonably expected to adversely affect any Product, including any declaratory judgment, opposition, or similar action alleging the invalidity, unenforceability, or non-infringement of any of the Rigel Patents or Joint Patents (collectively, "**Product Infringement**").

9.3.2 Enforcement Right. Rigel shall have the first right to bring and control any legal action in connection with such Product Infringement at its own expense as it reasonably determines appropriate. If Rigel (i) decides not to bring such legal action against a Product Infringement (the decision of which Rigel shall inform Kissei promptly) or (ii) Rigel otherwise fails to bring such legal action against a Product Infringement within ** of first becoming aware of such Product Infringement, Kissei shall have the right to bring and control any legal action in connection with such Product Infringement at its own responsibility and expense and in consultation with Rigel.

9.3.3 Collaboration. Each Party shall provide to the enforcing Party reasonable assistance in such enforcement, at such enforcing Party's request and expense, including to be named in such action if required by Applicable Laws to pursue such action. The enforcing Party shall keep the other Party regularly informed of the status and progress of such enforcement efforts, shall reasonably consider the other Party's comments on any such efforts, including determination of litigation strategy and filing of material papers to the competent court. The non-enforcing Party shall be entitled to separate representation in such matter by counsel of its own choice and at its own expense, but such Party shall at all times cooperate fully with the enforcing Party.

9.3.4 Expense and Recovery.

(a) Except as set forth in subsection 9.3.4(b) below, the enforcing Party shall be solely responsible for any cost and expenses incurred by such Party as a result of such enforcement action. If such Party recovers monetary damages in such enforcement action, such recovery shall be allocated **.

(b) Notwithstanding the foregoing, if ** is the enforcing Party against a Product Infringement in the Kissei Territory, ** shall have the option to share ** the cost and expense incurred by ** in such enforcement action, which option ** may exercise by providing written notice to ** within ** after receiving a notice from ** that it has determined to bring such action. If ** exercises such option, then (1) ** shall reimburse ** for ** of all costs and expenses incurred by ** in such enforcement action, within ** from the date of invoice for such costs and expenses provided by **; and (2) if ** recovers any monetary damages in such enforcement action, such recovery shall be allocated **.

9.3.5 Other Infringement. Except for Product Infringement as set forth above, each Party shall have the exclusive right to enforce its own Patent against any infringement anywhere in the world. For clarity, Rigel shall have the exclusive right to enforce (i) the Rigel Patents against any infringement in the Kissei Territory that is not a Product Infringement, and (ii) the Rigel Patents and Joint Patents against any infringement in the Rigel Territory, in each case at its own expense as it reasonably determines appropriate. The Parties shall discuss global enforcement strategy for the Rigel Patents and Kissei Patents, including the defense of validity and enforceability challenges arising from any enforcement action.

9.3.6 Infringement of Third Party Rights. If any Product used or sold by Kissei, its Affiliates, or Sublicensees becomes the subject of a Third Party's claim or assertion of infringement of any intellectual property rights in a jurisdiction within the Kissei Territory, Kissei shall promptly notify Rigel and the Parties shall promptly

meet to consider the claim or assertion and the appropriate course of action and may, if appropriate, agree on and enter into a "common interest agreement" wherein the Parties agree to their shared, mutual interest in the outcome of such potential dispute. Absent any agreement to the contrary, and subject to claims for indemnification under Article 11, each Party may defend itself from any such Third Party claim at its own cost and expense, provided, however, that the provisions of Section 9.3 shall govern the right of Kissei to assert a counterclaim of infringement of any Rigel Patents.

9.4 Patents Licensed From Third Parties. Each Party's rights under this Article 9 with respect to the prosecution and enforcement of any Rigel Patent, Kissei Patent and Joint Patent shall be subject to the rights (a) retained by any upstream licensor to prosecute and enforce such Patent, if such Patent is subject to an upstream license agreement; and (b) granted to any Third Party prior to such Patent becoming subject to the license grant under this Agreement.

9.5 Trademarks.

9.5.1 Product Trademarks. Subject to 9.5.3, each Party shall develop and adopt trademarks, including trade names, trade dresses, branding, and logos, to be used for the Products (the "**Product Marks**") in its own territory **; provided, however, that the Parties shall collaborate to have a global, worldwide trademark to be used on the Product where possible and in such cases Rigel shall own such global Product Mark, subject to the license granted to Kissei in Section 9.5.2. For clarity, Kissei may develop a trademark for its Commercialization of the Product in the Kissei Territory, which trademark is the notation of each national language in each country of the Kissei Territory parallel to Rigel's global, worldwide trademark in the Kissei Territory (the "**Kissei Product Mark**"), and Kissei shall own such Kissei Product Mark. Each Party shall own all Product Marks developed by such Party. Each Party shall be responsible for the registration, maintenance, defense, and enforcement of the Product Marks ** using counsel of its own choice in its respective territory. Kissei shall keep Rigel informed of material progress with regard to the registration, prosecution, maintenance, and defense, if any, of any Product Marks in the Kissei Territory, including content, timing, and jurisdiction of the filing of such Product Marks in the Kissei Territory.

9.5.2 Trademark License. Kissei has the option to use the Product Marks to Commercialize the Product in the Kissei Territory. In addition, unless prohibited by Applicable Laws, Kissei shall use Commercially Reasonable Effort to include Rigel's corporate trademark on the packaging and product information of the Products sold in the Kissei Territory to indicate that the Product is licensed from Rigel. Rigel hereby grants to Kissei a limited, royalty-free license to use Rigel's corporate trademark and Rigel Product Marks solely in connection with the Commercialization of the Product in the Kissei Territory under this Agreement. All use of the Product Marks and Rigel's corporate trademark shall comply with Applicable Laws and shall be subject to Rigel's prior review and written approval, provided that such Rigel's approval shall not be unreasonably withheld and delayed, and all goodwill in the Product Marks and Rigel's corporate trademark will inure to the benefit of Rigel . For clarity, Kissei shall also include its (or its Affiliate's or Sublicensee's, as applicable) corporate logo in the Product sold in the Kissei Territory and all goodwill in the Kissei Product Marks and Kissei's corporate trademark will inure to the benefit of Kissei.

9.5.3 Global Strategy. Where Rigel reasonably believes in good faith that a Product Mark developed by Kissei is not appropriate and conflicts with Rigel's global strategy for the Product, the Parties shall use reasonable commercial efforts to agree on an alternative Product Mark.

10. REPRESENTATIONS, WARRANTIES AND COVENANTS

10.1 Mutual Representations and Warranties. Each Party represents and warrants to the other that, as of the Effective Date: (a) it is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation, and has full corporate or other power and authority to enter into this Agreement and to carry out the provisions hereof, (b) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person or persons executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate or partnership action, (c) this Agreement is legally binding upon it, enforceable in accordance with its terms, and does not conflict with any agreement, instrument, or understanding, oral or written, to which it is a Party or by which it may be bound, nor violate any material law or regulation of any court, governmental body, or administrative or other agency having jurisdiction over it, and (d) it has the right to grant the licenses granted by it under this Agreement.

10.2 Covenants.

10.2.1 Conflicting Agreements. Neither Party shall enter into any agreement with any Third Party that would conflict with, limit or restrict such Party's ability to comply with this Agreement.

10.2.2 Employees, Consultants, and Contractors. Each Party covenants that it has obtained or will obtain written agreements from each of its employees, consultants, and contractors who perform Development activities pursuant to this Agreement, which agreements will obligate such persons to obligations of confidentiality and non-use and to assign (or, in the case of contractor, if the contracting Party is unable to obtain an assignment from such contractor despite good faith negotiation, to grant a license under) Inventions in a manner consistent with the provisions of this Agreement.

10.2.3 Debarment. Each Party represents, warrants, and covenants to the other Party that it is not debarred or disqualified under the U.S. Federal Food, Drug and Cosmetic Act, as may be amended, or comparable laws in any country or jurisdiction other than the U.S., and it does not, and will not during the Term, employ or use the services of any person who is debarred or disqualified, in connection with activities relating to any Product. In the event that either Party becomes aware of the debarment or disqualification or threatened debarment or disqualification of any person providing services to such Party, including the Party itself or its Affiliates or Sublicensees, that directly or indirectly relate to activities contemplated by this Agreement, such Party shall immediately notify the other Party in writing and such Party shall cease employing, contracting with, or retaining any such person to perform any such services.

10.2.4 Compliance. Each Party covenants as follows:

(a) In the performance of its obligations under this Agreement, each Party shall comply and shall cause its and its Affiliates' employees and contractors to comply with all Applicable Laws.

(b) Each Party and its and its Affiliates' employees and contractors shall not, in connection with the performance of their respective obligations under this Agreement, directly or indirectly through Third Parties, pay, promise, or offer to pay, or authorize the payment of, any money or give any promise or offer to give, or authorize the giving of anything of value to a Public Official or Entity or other person for purpose of obtaining or retaining business for or with, or directing business to, any person, including, each Party (and each Party represents and warrants that as of the Effective Date, such Party, and to its knowledge, its and its Affiliates' employees and contractors, have not directly or indirectly promised, offered, or provided any corrupt payment, gratuity, emolument, bribe, kickback, illicit gift, or hospitality or other illegal or unethical benefit to a Public Official or Entity or any other person in connection with the performance of such Party's obligations under this Agreement, and such Party covenants that it and its Affiliates' employees and contractors shall not, directly or indirectly, engage in any of the foregoing).

(c) Each Party and its Affiliates, and their respective employees and contractors, in connection with the performance of their respective obligations under this Agreement, shall not violate or cause the violation of the FCPA, Export Control Laws, or any other Applicable Laws, or otherwise cause any reputational harm to the other Party.

(d) Each Party shall immediately notify the other Party if it has any information or suspicion that there may be a violation of the FCPA, Export Control Laws, or any other Applicable Laws in connection with the performance of this Agreement or the Development, manufacture, or Commercialization of any Product.

(e) Each Party will have the right, upon reasonable prior written notice and during the other Party's regular business hours, to conduct at its own cost and expenses inspections of and to audit the other

Party's books and records in the event of a suspected violation or to ensure compliance with the representations, warranties, and covenants of this Section 10.2.4; provided, however, that in the absence of good cause for such inspections and audits, each Party exercise this right no more than annually.

(f) In the event that one Party has violated or been suspected of violating any of the representations, warranties, or covenants in this Section 10.2.4, such Party will cause its or its Affiliates' personnel or others working under its direction or control to submit to periodic training that it will provide on anti-corruption law compliance or other relevant compliance.

(g) Each Party shall have the right to suspend or terminate this Agreement in its entirety where there is a credible finding, after a reasonable investigation, that the other Party or its Affiliates or Sublicensees, in connection with the performance of such other Party's obligations under this Agreement, has engaged in chronic or material violations of the FCPA.

10.3 Additional Rigel Representations, Warranties, and Covenants. Rigel represents, warrants, and covenants, as applicable, to Kissei that, as of the Effective Date:

10.3.1 Schedule 10.3.1 lists all Patents Controlled by Rigel in the Kissei Territory as of the Effective Date that claim the composition of matter of Olutasidenib and all inventors of Inventions claimed in the Patents listed on **Schedule 10.3.1** have assigned their entire right, title, and interest in and to such inventions to Rigel or its applicable licensor and the inventors listed are correct and there are no claims or assertions in writing received by Rigel or Forma disputing the inventorship of such Patent or alleging that additional or alternative Inventors ought to be listed;

10.3.2 Rigel has the right to grant all rights and licenses it purports to grant to Kissei with respect to the Rigel Technology under this Agreement;

10.3.3 Rigel has not granted any liens or security interests on the Rigel Technology;

10.3.4 to Rigel's knowledge, Rigel has not received any written notice from a Third Party that the Development of any Product conducted by Rigel prior to the Effective Date has infringed any Patents of any Third Party;

10.3.5 Rigel has not as of the Effective Date, and will not during the Term, grant any right to any Third Party under the Rigel Technology that would conflict with the rights granted to Kissei hereunder;

10.3.6 no claim or action has been brought, or, to Rigel's knowledge, threatened in writing, by any Third Party alleging that the Rigel Patents are invalid or unenforceable, and no Rigel Patent is the subject of any interference, opposition, cancellation, or other protest proceeding;

10.3.7 to Rigel's knowledge, no Third Party is infringing or misappropriating or has materially infringed or misappropriated the Rigel Technology in the Kissei Territory;

10.3.8 Rigel is not aware of any Third Party Patents that would be necessary for Kissei to Develop or Commercialize the Product in the Field in the Kissei Territory;

10.3.9 to Rigel's knowledge, it has disclosed to Kissei the clinical and non-clinical data in Rigel's Control that is material to the evaluation of the safety, efficacy, and manufacturing process of the Product; and

10.3.10 to Rigel's knowledge, there are no issues or information, which to Rigel's knowledge and reasonable opinion, are reasonably likely to have a material impact on the Development of the Product that have not been fully disclosed to Kissei in the course of Kissei's due diligence.

10.4 Additional Kissei Representations, Warranties, and Covenants.

10.4.1 In connection with the performance of its obligations under this Agreement, Kissei shall comply and shall cause its and its Affiliates' employees and contractors to comply with Kissei's own anti-corruption and anti-bribery policy, a copy of which shall be provided to Rigel upon Rigel's written request.

10.4.2 Kissei represents, warrants, and covenants to Rigel that, as of the Effective Date, Kissei has not granted, and will not grant during the Term in the Rigel Territory or the Kissei Territory, any right to any Third Party under the Kissei Technology that would conflict with the rights granted to Rigel hereunder. Kissei further

represents, warrants, and covenants to Rigel that, as of the Effective Date, Kissei does not own or control any Kissei Patents.

10.5 Warranty Disclaimer. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, TO THE OTHER PARTY WITH RESPECT TO ANY TECHNOLOGY, INTELLECTUAL PROPERTY RIGHTS, RIGEL TECHNOLOGY, JOINT TECHNOLOGY, RIGEL PRODUCT MARK, PRODUCT, PROGRAM, GOODS, SERVICES, RIGHTS OR OTHER SUBJECT MATTER OF THIS AGREEMENT AND HEREBY DISCLAIMS ALL ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT WITH RESPECT TO ANY AND ALL OF THE FOREGOING , OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES, IN ALL CASES WITH RESPECT THERETO. EACH PARTY HEREBY DISCLAIMS ANY REPRESENTATION OR WARRANTY THAT THE FDA WILL APPROVE THE INITIAL NDA, THAT THE DEVELOPMENT, MANUFACTURE OR COMMERCIALIZATION OF ANY LICENSED PRODUCT PURSUANT TO THIS AGREEMENT SHALL BE SUCCESSFUL OR THAT ANY PARTICULAR SALES LEVEL WITH RESPECT TO ANY LICENSED PRODUCT SHALL BE ACHIEVED . Without limiting the foregoing, (a) neither Party represents or warrants that any data obtained from conducting Clinical Studies in one country or jurisdiction will comply with the laws and regulations of any other country or jurisdiction, and (b) neither Party represents or warrants the success of any study or test conducted pursuant to this Agreement or the safety or usefulness for any purpose of the technology it provides hereunder.

11. INDEMNIFICATION

11.1 Indemnification by Rigel. Rigel hereby agrees to defend, indemnify, and hold harmless Kissei and its Affiliates and their respective directors, officers, employees, and agents (each, a "**Kissei Indemnitee**") from and against any and all liabilities, expenses, and losses including any product liability, personal injury, property damage, including reasonable legal expenses and attorneys' fees (collectively, "**Losses**"), to which any Kissei Indemnitee may become subject as a result of any claim, demand, action, or other proceeding by any Third Party to the extent such Losses arise out of or result from: (a) the Development, use, Manufacture, handling, storage, Commercialization, or other disposition of Olutasidenib or any Product by Rigel or its Affiliates or licensees or the contractors of any of them (excluding any activities by or on behalf of Kissei or its Affiliates or Sublicensees), (b) the negligence or willful misconduct of any Rigel Indemnitee, or (c) the breach by Rigel of any warranty, representation, covenant, or agreement made by Rigel in this Agreement; except, in each case (a)-(c), to the extent such Losses arise out of any activities set forth in Section 11.2(a), (b), or (c) for which Kissei is obligated to indemnify any Rigel Indemnitee(s) under Section 11.2.

11.2 Indemnification by Kissei. Kissei hereby agrees to defend, indemnify, and hold harmless Rigel, its Affiliates, and licensees and their respective directors, officers, employees, and agents (each, a "**Rigel Indemnitee**") from and against any and all Losses to which any Rigel Indemnitee may become subject as a result of any claim, demand, action, or other proceeding by any Third Party to the extent such Losses arise out of: (a) the Development, use, handling, storage, Commercialization, or other disposition of Olutasidenib or any Product by Kissei or its Affiliates or Sublicensees or the contractor of any of them (excluding any activities by or on behalf of Rigel or its Affiliates or its licensor or other licensee than Kissei), (b) the negligence or willful misconduct of any Kissei Indemnitee, or (c) the breach by Kissei of any warranty, representation, covenant, or agreement made by Kissei in this Agreement; except, in each case (a)-(c), to the extent such Losses arise out of any activities set forth in Section 11.1(a), (b), or (c) for which Rigel is obligated to indemnify any Kissei Indemnitee(s) under Section 11.1.

11.3 Procedure. A party that intends to claim indemnification under this Article 11 (the "**Indemnitee**") shall promptly notify the indemnifying Party (the "**Indemnitor**") in writing of any Third Party claim, demand, action, or other proceeding (each, a "**Claim**") in respect of which the Indemnitee intends to claim such indemnification, and the Indemnitor shall have sole control of the defense or settlement thereof. The Indemnitee may participate at its expense in the Indemnitor's defense of and settlement negotiations for any Claim with counsel of the Indemnitee's own choice. The indemnity arrangement in this Article 11 shall not apply to amounts paid in settlement of any action with respect to a Claim if such settlement is effected without the consent of the Indemnitor, which consent shall not be unreasonably withheld or delayed. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any action with respect to a Third Party Claim shall only relieve the Indemnitor of its

indemnification obligations under this Article 11 if and to the extent the Indemnitor is actually prejudiced thereby. The Indemnitee shall cooperate fully with the Indemnitor and its legal representatives in the investigation of any action with respect to a Claim covered by this indemnification.

11.4 Insurance. Each Party, at its own expense, for a period until ** after expiration or termination of this Agreement, shall maintain commercial general liability insurance, including public and product liability and other appropriate insurance (e.g., contractual liability, bodily injury, property damage and personal injury coverage) (or self-insure) in an amount consistent with sound business practice and reasonable in light of its obligations under this Agreement during the Term, at a minimum equivalent to ** for any one claim or in the aggregate. Each Party shall provide a certificate of insurance (or evidence of self-insurance) evidencing such coverage to the other Party upon request. It is understood that such insurance shall not be construed to create any limit of either Party's obligations or liabilities with respect to its indemnification obligations hereunder. In the event of use by either Party of subcontractors, sublicensees, or any Third Party in the performance of such Party's obligations under the Agreement, such Party shall ensure that its subcontractor, sublicensee, or Third Party has a proper and adequate general liability insurance to cover its risks with respect to the other Party for damages mentioned above.

11.5 Limitation of Liability. NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL, OR PUNITIVE DAMAGES, INCLUDING LOST PROFITS, IN CONNECTION WITH THIS AGREEMENT OR ANY LICENSE GRANTED HEREUNDER, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES; PROVIDED, HOWEVER, THAT THIS SECTION 11.5 SHALL NOT BE CONSTRUED TO LIMIT EITHER PARTY'S INDEMNIFICATION OBLIGATIONS UNDER THIS ARTICLE 11 OR DAMAGES AVAILABLE AS A RESULT OF A PARTY'S WILLFUL MISCONDUCT OR A BREACH OF A PARTY'S EXCLUSIVITY OBLIGATIONS UNDER SECTION 2.9 OR CONFIDENTIALITY OBLIGATIONS UNDER ARTICLE 12.

12. CONFIDENTIALITY

12.1 Confidential Information. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, the Parties agree that, during the Term and for ** thereafter, the receiving Party shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as expressly provided for in this Agreement any Confidential Information of the disclosing Party, and both Parties shall keep confidential and, subject to the remainder of this Article 12, shall not publish or otherwise disclose the terms of this Agreement. Each Party may use the other Party's Confidential Information only to the extent required to accomplish the purposes of this Agreement, including exercising its rights or performing its obligations under this Agreement. Each Party will use at least the same standard of care as it uses to protect proprietary or confidential information of its own (but no less than reasonable care) to ensure that its employees, agents, consultants, contractors, and other representatives do not disclose or make any unauthorized use of the Confidential Information of the other Party. Each Party will promptly notify the other upon discovery of any unauthorized use or disclosure of the Confidential Information of the other Party.

12.2 Exceptions. The obligations of confidentiality and restriction on use under Section 12.1 will not apply to any information that the receiving Party can prove by competent written evidence: (a) is at the time of disclosure, or thereafter becomes, through no act or failure to act on the part of the receiving Party, generally known or available to the public; (b) is known by the receiving Party at the time of receiving such information, other than by previous disclosure of the disclosing Party, or its Affiliates, employees, agents, consultants, or contractors; (c) is disclosed to the receiving Party without restriction by a Third Party who has no obligation of confidentiality or limitations on use with respect thereto; or (d) is independently discovered or developed by the receiving Party without the use of or reference to the Confidential Information belonging to the disclosing Party.

12.3 Authorized Disclosure.

12.3.1 Each Party may disclose Confidential Information belonging to the other Party as expressly permitted by this Agreement or if and to the extent such disclosure is reasonably necessary in the following instances:

(a) filing, prosecuting, or maintaining Patents as permitted by this Agreement;

(b) Regulatory Filings for Products that such Party has a license or right to Develop or Commercialize hereunder in a given country or jurisdiction;

(c) prosecuting or defending litigation as permitted by this Agreement;

(d) complying with applicable court orders or governmental regulations, including regulations promulgated by securities exchanges; and

(e) disclosure to its and its Affiliates' employees, consultants, contractors, agents, licensees and sublicensees, in each case on a need-to-know basis, in connection with the Development, manufacture, or Commercialization of Olutasidenib and Products in accordance with the terms of this Agreement, in each case under written obligations of confidentiality and non-use at least as stringent as those herein, and in the case of Rigel, disclosure to its licensor Forma Therapeutics, Inc. (now Novo Nordisk) to the extent required to comply with the Rigel-Forma Agreement; and

(f) disclosure to actual and bona fide potential investors, acquirers, licensees, sublicensees and other financial or commercial partners solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition, or collaboration, in each case under written obligations of confidentiality and non-use at least as stringent as those herein, provided that the disclosing Party redacts the financial terms and other provisions of this Agreement that are not reasonably required to be disclosed in connection with such potential investment, acquisition, or collaboration, which redaction shall be prepared in consultation with the other Party.

12.3.2 Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to Section 12.3.1(c) or 12.3.1(d), it will, except where impracticable, give reasonable advance notice to the other Party of such disclosure and use the same diligent efforts to secure confidential treatment of such Confidential Information as such Party would use to protect its own confidential information, but in no event less than reasonable efforts. In any event, the Parties agree to take all reasonable action to avoid disclosure of Confidential Information hereunder. Any information disclosed pursuant to Section 12.3.1(c) or 12.3.1(d) shall remain Confidential Information and subject to the restrictions set forth in this Agreement, including the foregoing provisions of this Article 12. For clarity, Kissei shall not disclose the Confidential Information of Rigel to an Affiliate or any Third Party for use by such Affiliate or Third Party to Develop, Manufacture or Commercialize a Generic Product without prior written consent from Rigel, unless required by Applicable Laws.

12.3.3 Each Party recognizes that the value to the other Party of the transactions under this Agreement depend, in part, on each Party protecting the secrecy of its Know-How. Therefore, without limiting any Party's rights to license its Know-How, subject to the terms of this Agreement, in any way it chooses, each Party shall use Commercially Reasonable Efforts to protect the confidentiality of its Know-How as determined in such Party's reasonable business judgment.

12.4 Publications.

12.4.1 Each Party may have the right to review and comment on any material proposed for disclosure or publication by the other Party (the "**Publishing Party**") regarding results of and other information regarding the Publishing Party's Development activities during the Term with respect to Olutasidenib and Product, whether by oral presentation, manuscript, or abstract (such materials, the "**Publication Materials**"), as follows:

(a) If Rigel undertakes Development activities in the Rigel Territory that result in Publication Materials, including with respect to any global Registrational Study, then Rigel shall have the sole right to disclose such Publication Materials and Kissei shall have no right to review such Publication Materials;

(b) If Kissei undertakes Development activities in the Kissei Territory that result in Publication Materials, then Kissei shall have the right to disclose such Publication Materials, subject to Rigel's right to review such Publication Materials as set forth in Sections 12.4.2 and 12.4.3; and

(c) If Rigel and Kissei undertake joint Development activities anywhere in the world that result in Publication Materials, then Rigel shall have the right to disclose such Publication Materials, subject to Kissei's right to review such Publication Materials as set forth in Sections 12.4.2 and 12.4.3, and Kissei would have the right to disclose such Publication Materials, subject to Rigel's prior consent.

12.4.2 Before any such Publication Material is submitted for publication, or presentation of any such Publication Material is made, the Publishing Party shall deliver a complete copy of the Publication Material proposed for disclosure to the other Party (the "**Reviewing Party**") at least ** prior to submitting the Publication Material to a publisher or initiating any other disclosure, or as close to these time frames as reasonably possible. The

Reviewing Party shall review any such Publication Material and give its comments to the Publishing Party within ** of the receipt of such Publication Material. With respect to oral presentation materials and abstracts, the Reviewing Party shall make reasonable efforts to expedite review of such materials and abstracts, and shall return such items as soon as practicable to the Publishing Party with comments, if any. Subject to Section 12.4.3, following the expiration of the applicable time period for review, the Publishing Party shall be free to submit such proposed manuscript for publication or presentation materials for public disclosure, and does not need to follow this process for subsequent publications or presentations of the same data.

12.4.3 If the Reviewing Party notifies the Publishing Party within the applicable time period set forth in subsection (a) above that such publication or presentation, in the Reviewing Party's reasonable judgment:

(a) contains an invention for which the Reviewing Party desires to obtain patent protection, the Publishing Party shall delay such publication or presentation for a period of up to ** (or such other time period agreed by the Parties in writing) to permit the preparation and filing of a patent application for such invention, or

(b) contains any Confidential Information of the Reviewing Party, or could be expected to have an adverse effect on the commercial value of any Confidential Information disclosed by the Reviewing Party to the Publishing Party, the Parties shall attempt to agree on revisions to the applicable disclosure so as to preserve both the commercial value of such Confidential Information and the scientific merit of such disclosure, provided that if and to the extent the Parties are unable to agree, the Publishing Party shall delete such Confidential Information from the proposed publication or presentation.

12.5 Publicity and Press Release; Public Disclosures.

12.5.1 It is understood that each Party will issue a joint press release announcing this Agreement in a form agreed by the Parties, and subsequent press releases relating to this Agreement or activities hereunder. The Parties agree to consult with each other reasonably and in good faith with respect to the text and timing of any subsequent press releases prior to the issuance thereof, to the extent practicable, provided that a Party may not unreasonably withhold, condition, or delay its input to such releases by more than **, and that either Party may issue such press releases or, subject to Section 16.5.2, make such disclosures to the SEC or other applicable agency as it determines, based on advice of counsel, is reasonably necessary to comply with Applicable Laws or for appropriate market disclosure. In addition, following the initial joint press release announcing this Agreement, either Party shall be free to disclose, without the other Party's prior written consent, the existence of this Agreement, the identity of the other Party and those terms of the Agreement which have already been publicly disclosed in accordance with this Section 12.5.

12.5.2 Each Party shall provide the other Party with advance notice of legally required disclosures to the extent practicable. The Parties will consult with each other on the provisions of this Agreement to be redacted in any filings made by a Party with the SEC or other applicable agency or as otherwise required by Applicable Laws; provided that each Party shall have the right to make any such filing as it reasonably determines necessary under Applicable Laws.

12.6 Prior Confidentiality Agreement. As of the Effective Date, the terms of this Article 12 shall supersede any prior non-disclosure, secrecy, or confidentiality agreement between the Parties (or their Affiliates) relating to the subject of this Agreement, including the Confidentiality Agreement. Any information disclosed pursuant to any such prior agreement shall be deemed Confidential Information under this Agreement.

12.7 Equitable Relief. Given the nature of the Confidential Information and the competitive damage that a Party would suffer upon unauthorized disclosure, use, or transfer of its Confidential Information to any Third Party, the Parties agree that monetary damages may not be a sufficient remedy for any breach of this Article 12. In addition to all other remedies, a Party shall be entitled to seek specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this Article 12.

12.8 Survival. The provisions in this Article 12 shall survive the expiration or the termination of this Agreement for a period of ** thereafter.

13. TERM AND TERMINATION

13.1 Term. This Agreement shall commence on the Effective Date and shall continue until terminated as provided in this Article 13 (the "**Term**").

13.2 Termination for Cause.

13.2.1 Material Breach. Each Party shall have the right to terminate this Agreement immediately in its entirety upon written notice to the other Party if such other Party materially breaches this Agreement and has not cured such breach to the reasonable satisfaction of the other Party within ** after notice of such breach from the non-breaching Party.

13.2.2 Bankruptcy. Each Party shall have the right to terminate this Agreement immediately in its entirety upon written notice to the other Party if such other Party makes a general assignment for the benefit of creditors, files an insolvency petition in bankruptcy, petitions for or acquiesces in the appointment of any receiver, trustee, or similar officer to liquidate or conserve its business or any substantial part of its assets, commences under the laws of any jurisdiction any proceeding involving its insolvency, bankruptcy, reorganization, adjustment of debt, dissolution, liquidation, or any other similar proceeding for the release of financially distressed debtors, or becomes a party to any proceeding or action of the type described above and such proceeding is not dismissed within ** after the commencement thereof.

13.2.3 Patent Challenge. Rigel shall have the right to terminate this Agreement immediately in its entirety upon written notice to Kissei if Kissei or any of its Affiliates or Sublicensees directly, or indirectly through any Third Party, commences any interference or opposition proceeding with respect to, challenges the validity or enforceability of, or opposes any extension of or the grant of a supplementary protection certificate with respect to, any Rigel Patent.

13.2.4 Safety Reasons. Either Party shall have the right to terminate or suspend its Development and/or Commercialization of the Product in its Territory upon written notice to the other Party if the terminating Party reasonably determines, based upon additional information that becomes available or an analysis of the existing information at any time, that the medical risk/benefit of the Product is so unfavorable that it would be incompatible with the welfare of patients to Develop or Commercialize or to continue to Develop or Commercialize such Product. Prior to any such termination, the terminating Party shall comply with such internal review and management approval processes as it would normally follow in connection with the termination of the development and commercialization of its own products for safety reasons. The terminating Party shall document the decisions of such committees or members of management and the basis therefor and shall make such minutes and documentation available to the other Party promptly upon written request. In the event that Rigel terminates its Development or Commercialization of the Product according to this Section 13.2.4, and Kissei wishes to continue to Develop and/or Commercialize the Product in the Field in the Kissei Territory, Kissei shall notify Rigel in writing and any such continuation by Kissei shall occur only subject to an amendment to this Agreement to be negotiated between the Parties.

13.2.5 Termination by Kissei for Other Causes. Kissei shall have the right to terminate this Agreement in its entirety immediately by delivery of written notice due to (i) the PMDA's recommendation prohibiting further Development of the Product **, (ii) PMDA's recommendation to hold Companion Diagnostic Development indefinitely, (iii) material breach by the CDx Company of its obligation to create or develop the Companion Diagnostic resulting in Kissei's termination of the CDx Company Agreement as a result of such breach, (iv) the termination by the CDx Company of the CDx Company Agreement **, and (v) PMDA's recommendation not to submit MAA for the Product.

13.3 Termination without Cause.

13.3.1 Prior to **. After the **, Kissei shall have the right to terminate this Agreement in its entirety without cause upon ** prior written notice to Rigel.

13.3.2 After **. Following ** the Product in the Kissei Territory, Kissei shall have the right to terminate this Agreement in its entirety without cause upon ** prior written notice to Rigel.

13.3.3 After the Commercialization Term. Either Party shall have the right to terminate this Agreement, on a Product-by-Product and country-by-country basis, without cause upon ** prior written notice to the other Party so long as such termination becomes effective on or after the end of the Commercialization Term for such Product in such country.

13.4 Effects of Termination. If Kissei, its Affiliates and/or Sublicensees continues to Commercialize the Product after the termination of this Agreement pursuant to Section 13.3.3, Kissei's obligations to pay Transfer Price under Section 8.4.4 and Section 8.4.5 shall survive such termination. Upon the termination of this Agreement for any other reason, the following subsections 13.4.1-13.4.9 will apply. For clarity, during the pendency of any termination notice period, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder.

13.4.1 Licenses. All licenses granted by Rigel to Kissei will automatically terminate, including all sublicenses granted by Kissei to any Sublicensee. Except in the event of termination by Kissei under Section 13.2.1 for material breach by Rigel, the licenses granted by Kissei to Rigel shall survive in perpetual and fully-paid-up basis following such termination and shall automatically become worldwide.

13.4.2 Regulatory Materials; Data. Within ** after the effective date of termination, Kissei shall transfer and assign to Rigel, ** all Regulatory Filings and Regulatory Approvals for the Product, Data from all preclinical, non-clinical, and Clinical Studies of the Product conducted by or on behalf of Kissei, its Affiliates, or Sublicensees, and all pharmacovigilance data (including all adverse event data) on the Product. In addition, at Rigel's reasonable request, Kissei shall provide Rigel with Commercially Reasonable assistance with any inquiries and correspondence with Regulatory Authorities regarding the Product in the Kissei Territory, such assistance shall be limited to a period of ** after such termination.

13.4.3 Development Wind-Down. Kissei shall either, as directed by Rigel, (i) wind-down any ongoing Development activities (including any Clinical Studies) of Kissei or its Affiliates and Sublicensees with respect to any Product in the Kissei Territory in an orderly fashion at Kissei's cost or (ii) promptly transfer such Development activities to Rigel or its designee, ** in each case in compliance with all Applicable Laws.

13.4.4 Cost of Ongoing Trials. If there is any ongoing Clinical Study of the Product under the Development Plan for which the Parties are sharing costs, then Kissei shall continue to share the cost of such Clinical Study until **. The remaining costs from ** until completion of such Clinical Study (or early termination of such Clinical Study by Rigel) shall be borne entirely by Rigel following **.

13.4.5 Commercial Wind-Down. The Parties agree that Kissei shall (i) continue certain ongoing Commercial activities of Kissei and its Affiliates and Sublicensees with respect to any Product in the Kissei Territory for a period of up to ** after the effective date of termination and (ii) handoff such Commercial activities to Rigel or its designee, on a timetable to be set by the Parties, not to exceed ** after the effective date of termination, and in compliance with all Applicable Laws. During such commercial wind-down period, Kissei shall continue to book sales and pay the Transfer Price to Rigel in accordance with Section 8.4. Except as necessary to conduct the foregoing activities as directed by Rigel, Kissei shall immediately discontinue its (and shall ensure that its Affiliates and Sublicensees immediately discontinue their) promotion, marketing, offering for sale, and servicing of the Product and its use of all Product Marks. In addition, Kissei shall immediately deliver to Rigel ** all samples, demonstration equipment, sales materials, catalogs, and literature of Rigel in Kissei's possession or control.

13.4.6 Transition Assistance. Kissei shall use Commercially Reasonable Efforts to seek an orderly transition of the Development and Commercialization of Olutasidenib and Products to Rigel or its designee. Except in the event of termination by Kissei under Section 13.2.1, Kissei shall, ** provide reasonable consultation and assistance for a period of no more than ** after the effective date of termination for the purpose of transferring or transitioning to Rigel all Kissei Know-How not already in Rigel's possession. At Rigel's request, Kissei will transfer all then-existing commercial arrangements relating to the Product that Kissei is able, using Commercially Reasonable Efforts, to transfer or transition to Rigel or its designee, in each case, to the extent reasonably necessary for Rigel to continue the Development or Commercialization of Olutasidenib and Products in the Kissei Territory. If any such contract between Kissei and a Third Party is not assignable to Rigel or its designee (whether by such contract's terms or because such contract does not relate specifically to the Product) but is otherwise reasonably necessary for Rigel to continue the Development or Commercialization of Olutasidenib and Products in the Kissei Territory, or if Kissei is performing such work for Olutasidenib and Product itself (and thus there is no contract to assign), then Kissei shall reasonably cooperate with Rigel to negotiate for the continuation of such services for Rigel from such entity, or Kissei shall use Commercially Reasonable Efforts to continue to perform such work for Rigel, as applicable, for a reasonable period (not to exceed **) after the effective date of termination at Rigel's cost until Rigel establishes an alternate, validated source of such services.

13.4.7 Remaining Inventories. Other than termination for safety reasons pursuant to Section 13.2.4, Kissei shall have the right to sell out the inventory of the Product held by Kissei as of the notice date of termination but such right shall expire on ** of the effective date of termination (as further described in Section 13.4.5), subject to Kissei's payment obligations to Rigel under Article 8 with respect to such sales.

13.4.8 Trademarks. The Trademark license granted to Kissei under Section 9.5.2 shall terminate and Kissei shall cease immediately the use of all Rigel Product Marks. Unless this Agreement is terminated pursuant to Section 13.3.3, Kissei shall transfer and assign to Rigel, ** all Kissei Product Marks.

13.4.9 Non-Compete. Following any termination of this Agreement by Rigel pursuant to Section 13.2 or by Kissei pursuant to Section 13.3, neither Kissei nor any of its Affiliates shall (directly or indirectly, either with or without a bona fide collaborator or any other Third Party) commercialize any Competing Product for a period of ** following the effective date of such termination.

13.5 Confidential Information. Upon expiration or termination of this Agreement in its entirety, except to the extent that a Party obtains or retains the right to use the other Party's Confidential Information, each Party shall promptly return to the other Party, or delete or destroy, all relevant records and materials in such Party's possession or control containing Confidential Information of the other Party; provided that such Party may keep one copy of such materials for archival purposes only subject to continuing confidentiality obligations. All Kissei Data and Regulatory Filings assigned to Rigel upon termination of this Agreement will be deemed Rigel's Confidential Information and no longer Kissei's Confidential Information.

13.6 Survival. Expiration or termination of this Agreement shall not relieve the Parties of any obligation or right accruing prior to such expiration or termination. Except as set forth below or elsewhere in this Agreement, the obligations and rights of the Parties under the following provisions of this Agreement shall survive expiration or termination of this Agreement: Articles 1 (Definitions), 8 (with respect to payment obligations accrued prior to such expiration or termination and/or during the Extended Commercialization Term), 9 (Intellectual Property), 10, (Representations, Warranties and Covenants), 11 (Indemnification), 13 (Term and Termination), 14 (Dispute Resolution), and 15 (General Provisions).

13.7 Exercise of Right to Terminate. All rights and obligations of a Party accrued prior to the effective date of a termination (including the rights to receive reimbursement for costs incurred prior to the effective date of such termination and payments accrued or due prior to the effective date of such termination) shall survive such termination.

13.8 Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by one Party to the other Party are, and will otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws. The Parties agree that a Party that is a licensee of such rights under this Agreement will retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against a Party to this Agreement under the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws, the other Party will be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, and same, if not already in its possession, will be promptly delivered to it (a) upon any such commencement of a bankruptcy or insolvency proceeding upon its written request therefor, unless the bankrupt Party elects to continue to perform all of its obligations under this Agreement, or (b) if not delivered under (a) above, following the rejection of this Agreement by or on behalf of the bankrupt Party upon written request therefor by the other Party.

14. DISPUTE RESOLUTION

14.1 Objective. The Parties recognize that disputes as to matters arising under or relating to this Agreement or either Party's rights and obligations hereunder may arise from time to time. It is the objective of the Parties to establish procedures to facilitate the resolution of such disputes in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Article 14 to resolve any such dispute if and when it arises.

14.2 Executive Mediation. The Parties shall attempt to settle any dispute, controversy, or claim that arises out of, or relates to, any provision of the Agreement ("**Disputed Matter**") by first referring the Disputed Matter to the Executive Officers **. Either Party may initiate such informal dispute resolution by sending written notice of the Disputed Matter to the other Party, and, within ** after such notice, the Executive Officers ** shall meet for attempted resolution by good faith negotiations. If the Executive Officers ** are unable to resolve such dispute within t** of their first meeting for such negotiations, either Party may seek to have such dispute resolved in accordance with Section 14.3 below.

14.3 Dispute Resolution.

14.3.1 If the Parties are unable to resolve a Disputed Matter using the process described in Section 14.2, then a Party seeking further resolution of the Disputed Matter will submit the Disputed Matter to resolution by final and binding arbitration. Whenever a Party decides to institute arbitration proceedings, it will give written notice to that effect to the other Party. Arbitration will be held in ** and administered by the International Chamber of Commerce pursuant to its ICC International Arbitration Rules then in effect (the "**Rules**"), except as otherwise provided herein and applying the substantive law specified in Section 15.1. The arbitration will be conducted by a panel of three (3) arbitrators appointed in accordance with the Rules; provided that each Party will, within ** after the institution of the arbitration proceedings, appoint an arbitrator, and such arbitrators will together, within **, select a third (3rd) arbitrator as the chairperson of the arbitration panel. Each arbitrator must have significant business or legal experience in the pharmaceutical business. If the two (2) initial arbitrators are unable to select a third (3rd) arbitrator within such ** period, the third (3rd) arbitrator will be appointed in accordance with Rules. After conducting any hearing and taking any evidence deemed appropriate for consideration, the arbitrators will be requested to render their opinion within ** of the final arbitration hearing. No panel of arbitrators will have the power to award damages excluded pursuant to Section 11.5 under this Agreement and any arbitral award that purports to award such damages is expressly prohibited and void *ab initio*. Decisions of the panel of arbitrators that conform to the terms of this Section 14.3 will be final and binding on the Parties and judgment on the award so rendered may be entered in any court of competent jurisdiction. The losing Party, as determined by the panel of arbitrators, will pay all of the ICC administrative costs and fees of the arbitration and the fees and costs of the arbitrators, and the arbitrators will be directed to provide for payment or reimbursement of such fees and costs by the losing Party. If the panel of arbitrators determines that there is no losing Party, the Parties will each bear one-half of those costs and fees and the arbitrators' award will so provide. Notwithstanding the foregoing, each Party shall bear its own attorneys' fees, expert or witness fees, and any other fees and costs, and no such fees or costs will be shifted to the other Party.

14.3.2 Notwithstanding the terms of and procedures set forth in Section 14.2 or 14.3.1, any applications, motions, or orders to show cause seeking temporary restraining orders, preliminary injunctions, or other similar preliminary or temporary legal or equitable relief ("**Injunctive Relief**") concerning a Disputed Matter (including Disputed Matters arising out of a potential or actual breach of the confidentiality and non-use provisions in Article 12) may immediately be brought in the first instance and without invocation or exhaustion of the procedures set forth in subsections (a) and (b) for hearing and resolution in and by any court of competent jurisdiction. Alternatively, a party seeking Injunctive Relief may immediately institute arbitral proceedings without invocation or exhaustion of the procedures set forth in subsections (a) and (b), and any such Injunctive Relief proceedings will be administered by the ICC pursuant to its ICC emergency arbitration procedures then in effect and applying the substantive law specified in Section 15.1. In either event, once the Injunctive Relief proceedings have been conducted and a decision is rendered thereon by the court or arbitral forum, the Parties shall, if the Disputed Matter is not finally resolved by the Injunctive Relief, proceed to resolve the Disputed Matter in accordance with the terms of Section 14.2 and 14.3.1.

14.3.3 Notwithstanding the foregoing, this Section 14.3 shall not apply to any dispute, controversy, or claim that concerns (i) the validity, enforceability, or infringement of a patent, trademark, or copyright; or (ii) any antitrust, anti-monopoly, or competition law or regulation, whether or not statutory. Disputes regarding the

foregoing shall be brought in a court of competent jurisdiction in which such patent or trademark or copyright was granted or arose, or in which such law or regulation applies, in each case as applicable.

15. GENERAL PROVISIONS

15.1 Governing Law. This Agreement, and all questions regarding the existence, validity, interpretation, breach, or performance of this Agreement, shall be governed by, and construed and enforced in accordance with, the laws of the State of New York, U.S., without reference to its conflicts of law principles.

15.2 Entire Agreement; Modification. This Agreement, including the exhibits, is both a final expression of the Parties' agreement and a complete and exclusive statement with respect to all of its terms. This Agreement supersedes all prior and contemporaneous agreements and communications, whether oral, written, or otherwise, concerning any and all matters contained herein. This Agreement may only be modified or supplemented in a writing expressly stated for such purpose and signed by the Parties to this Agreement.

15.3 Relationship Between the Parties. The Parties' relationship, as established by this Agreement, is solely that of independent contractors. This Agreement does not create any partnership, joint venture, or similar business relationship between the Parties. Neither Party is a legal representative of the other Party, and neither Party can assume or create any obligation, representation, warranty, or guarantee, express or implied, on behalf of the other Party for any purpose whatsoever.

15.4 Non-Waiver. The failure of a Party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement shall neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance. Any waiver by a Party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time and shall be signed by such Party.

15.5 Assignment. Except as expressly provided hereunder, neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred by either Party without the prior written consent of the other Party (which consent shall not be unreasonably withheld); provided, however, that either Party may assign or otherwise transfer this Agreement and its rights and obligations hereunder without the other Party's consent:

15.5.1 in connection with the transfer or sale of all or substantially all of the business or assets of such Party relating to Olutasidenib and Products to a Third Party, whether by merger, consolidation, divesture, restructure, sale of stock, sale of assets, or otherwise, provided that in the event of any such transaction (whether this Agreement is actually assigned or is assumed by the acquiring Party by operation of law (e.g., in the context of a reverse triangular merger)), the intellectual property rights of the acquiring Party to such transaction (if other than one of the Parties to this Agreement) shall not be included in the technology licensed hereunder; or

15.5.2 to an Affiliate, provided that the assigning Party shall remain liable and responsible to the non-assigning Party hereto for the performance and observance of all such duties and obligations by such Affiliate, and provided further that if the entity to which this Agreement is assigned ceases to be an Affiliate of the assigning Party, the Agreement shall be automatically assigned back to the assigning Party or its successor.

The rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties specified above, and the name of a Party appearing herein will be deemed to include the name of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Section 15.5. Any assignment not in accordance with this Section 15.5 shall be null and void. For clarity, neither Party's rights and obligations under this Agreement shall be affected by the other Party's assignment of this Agreement.

15.6 Severability. If, for any reason, any part of this Agreement is adjudicated invalid, unenforceable, or illegal by a court of competent jurisdiction, such adjudication shall not, to the extent feasible, affect or impair, in whole or in part, the validity, enforceability, or legality of any remaining portions of this Agreement. All remaining portions shall remain in full force and effect as if the original Agreement had been executed without the invalidated, unenforceable, or illegal part.

15.7 Notices. Any notice to be given under this Agreement must be in writing and delivered either in person, by (a) air mail (postage prepaid) requiring return receipt, (b) overnight courier, (c) facsimile confirmed thereafter by any of the foregoing, or (d) email , to the Party to be notified at its address(es) given below, or at any

address such Party may designate by prior written notice to the other in accordance with this Section 15.7. Notice shall be deemed sufficiently given for all purposes upon the earliest of: (i) the date of actual receipt, (ii) if air mailed, ** after the date of postmark, (iii) if delivered by overnight courier, the next day the overnight courier regularly makes deliveries, or (iv) if sent by facsimile or email, the date of confirmation of receipt if during the recipient's normal business hours, otherwise the next Business Day.

If to Kissei, notices must be addressed to:

Kissei Pharmaceutical Co., Ltd
1-8-9 Nihonbashi-Muromachi,
Chuo-ku, Tokyo 103-0022 Japan
Attention: **
Facsimile: **Email: **

with a copy to
Kissei Pharmaceutical Co., Ltd.
19-48 Yoshino, Matsumoto-City
Nagano-prefecture, 399-8710 Japan
Attention: **
Facsimile: **
Email: **

If to Rigel, notices must be addressed to:

Rigel Pharmaceuticals, Inc.
611 Gateway Boulevard, Suite 900
South San Francisco, CA 94080
USA
Attention: **
Email: **

15.8 Force Majeure. Each Party shall be excused from liability for the failure or delay in performance of any obligation under this Agreement (other than failure to make payment when due) by reason of any event beyond such Party's reasonable control including Acts of God, fire, flood, explosion, earthquake, pandemic flu, or other natural forces, war, civil unrest, acts of terrorism, accident, destruction or other casualty, any lack or failure of transportation facilities, any lack or failure of supply of raw materials, or any other event similar to those enumerated above. Such excuse from liability shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the Party has not caused such event(s) to occur and uses reasonable efforts to overcome such event. Notice of a Party's failure or delay in performance due to force majeure must be given to the other Party within ** after its occurrence. All delivery dates under this Agreement that have been affected by force majeure shall be tolled for the duration of such force majeure. In no event shall any Party be required to prevent or settle any labor disturbance or dispute.

15.9 Interpretation. The headings of clauses contained in this Agreement preceding the text of the sections, subsections, and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Agreement or have any effect on its interpretation or construction. All references in this Agreement to the singular shall include the plural where applicable. Unless otherwise specified, references in this Agreement to any Article shall include all Sections, subsections, and paragraphs in such Article, references to any Section shall include all subsections and paragraphs in such Section, and references in this Agreement to any subsection shall include all paragraphs in such subsection. The word "including" and similar words means including without limitation. The word "or" means "and/or" unless the context dictates otherwise because the subjects of the conjunction are, or are intended to be, mutually exclusive. The words "herein", "hereof", and "hereunder" and other words of similar import refer to this Agreement as a whole and not to any particular Section or other subdivision. All references to days in this Agreement mean calendar days, unless otherwise specified. Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either Party, irrespective of which Party may be deemed to have caused the ambiguity or uncertainty to exist. This Agreement has been prepared in the English language and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder,

and all written, electronic, oral, or other communications between the Parties regarding this Agreement shall be in the English language.

15.10 Counterparts; Electronic or Facsimile Signatures. This Agreement may be executed in any number of counterparts, each of which shall be an original, but all of which together shall constitute one instrument. This Agreement may be executed and delivered electronically or by facsimile and upon such delivery such electronic or facsimile signature will be deemed to have the same effect as if the original signature had been delivered to the other Party.

{SIGNATURE PAGE FOLLOWS}

IN WITNESS WHEREOF, the Parties hereto have caused this Collaboration and License Agreement to be executed and entered into by their duly authorized representatives as of the Effective Date.

RIGEL PHARMACEUTICALS, INC.	**KISSEI PHARMACEUTICAL CO. LTD.**
By: /s/ Raul R. Rodriguez	By: /s/ Mutsuo Kanzawa
Name: Raul R. Rodriguez	Name: Mutsuo Kanzawa
Title: President and CEO	Title: Chairman and CEO

Schedule 10.3.1
Rigel Patents

**

Schedule 1.134
Rigel Product Marks

**

Schedule 4.3
Initial Development Plan and Budget

**

Exhibit 10.2

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [**], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

SUPPLY AGREEMENT

This **Supply Agreement** (the "**Supply Agreement**") is entered into as of September 3, 2024 (the " **Effective Date**") by and between **Rigel Pharmaceuticals, Inc.**, a Delaware company having an address at 611 Gateway Blvd., Suite 900, South San Francisco, CA 94080, USA ("**Rigel**") and **Kissei Pharmaceutical Co. Ltd.**, a Japanese company having an address at 19-48 Yoshino, Matsumoto, Nagano 399-8710, Japan ("**Kissei**"). Rigel and Kissei may be referred to herein individually as a "**Party**" or collectively as the "**Parties**".

RECITALS

Whereas, Rigel, a biopharmaceutical company, has developed its proprietary compound olutasidenib, also known as REZLIDHIA® in the United States, which has been approved by the FDA for the treatment of adults with acute myeloid leukemia (AML) with an isocitrate dehydrogenase-1 (IDH1) mutation when the disease has come back (relapsed) or has not improved after one or more treatments (refractory) **;

Whereas, Rigel and Kissei are parties to a certain Collaboration and License Agreement of even date hereof (the "**Collaboration and License Agreement**"), under which Rigel has granted Kissei the right to develop and commercialize olutasidenib in the Kissei Territory; and

Whereas, the Collaboration and License Agreement contemplates that Rigel will manufacture, or have manufactured, and supply olutasidenib to Kissei for development and commercial use, and Rigel is willing to manufacture and supply olutasidenib to Kissei, on the terms and conditions set forth below.

Now, **Therefore**, in consideration of the foregoing premises and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

ARTICLE 1
DEFINITIONS

Capitalized terms used in this Supply Agreement but not defined herein shall have the meanings set forth in the Collaboration and License Agreement.

1.1 "**Batch**" means the quantity of a Product produced in a single production run of such Product.

1.2 "**Business Day**" means a day that is not a Saturday, Sunday, or a day on which banking institutions in ** are authorized by Applicable Law to remain closed.

1.3 "**Claim**" had the meaning set forth in Section 9.3.

1.4 "**Collaboration and License Agreement**" has the meaning set forth in the Recitals.

1.5 "**Compound**" means olutasidenib, having the chemical structure set forth in **Exhibit A**.

1.6 "**Drum**" means the quantity of Product, which is a portion of a Batch, supplied by Rigel to Kissei as mutually agreed upon in the Specification.

1.7 "**Finish Manufacture**" means the manufacture of Finished Product from Product supplied by Rigel to Kissei (in either Batch or Drum quantity) and in the form (such as brite stock in naked bottles or bulk capsules) mutually agreed upon in the Specification.

1.8 "**Finished Product**" means the Product in appropriate final form, packaged and labeled and ready for its intended use (i.e., sale to the end-user, use in any Clinical Trial or other Development work, or use as a sample).

1.9 "**GMP**" means the current minimum standards for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug as specified by applicable laws of the relevant countries at the time of manufacturing conducted in accordance with this Supply Agreement, defined under (a) 21 C.F.R. Part 210 and 211, and (b) equivalent law or regulations in any other applicable jurisdiction such as in the Kissei Territory.

1.10 "**Indemnitee**" has the meaning set forth in Section 9.3.

1.11 "**Indemnitor**" has the meaning set forth in Section 9.3.

1.12 "**Information**" means any data, results, technology, business, or financial information, or information of any type whatsoever, in any tangible or intangible form, including know-how, trade secrets, practices, techniques, methods, processes, inventions, developments, specifications, formulae, software, algorithms, marketing reports, expertise, technology, test data (including pharmacological, biological, chemical, biochemical, clinical test data, and data resulting from non-clinical studies), CMC information, stability data, and other study data and procedures.

1.13 "**Kissei Indemnitee**" has the meaning set forth in Section 9.1.

1.14 "**Losses**" has the meaning set forth in Section 9.1.

1.15 "**Manufacture**" means all activities related to the manufacturing of the Product and its placebo (if applicable) in fill and finished form but without final packaging or labeling, including quality assurance activities related to manufacturing and release of product, ongoing stability tests, and regulatory activities related to any of the foregoing. "**Manufacturing**" has a correlative meaning.

1.16 "**Order Forecast**" has the meaning set forth in Section 2.2(a).

1.17 "**Product**" has the meaning set forth in Section 1.110 of the Collaboration and License Agreement.

1.18 "**Quality Agreement**" has the meaning set forth in Section 2.6.

1.19 "**Rigel Indemnitee**" has the meaning set forth in Section 9.2.

1.20 "**Specification**" means the written specifications for the Product. Specifications may be required to be different for a Product for use in different countries due to individual Regulatory Authority requirements in such countries.

1.21 "**Term**" has the meaning set forth in Section 10.1.

1.22 "**Transfer Price**" has the meaning set forth in Section 3.13.1.

ARTICLE 2
PRODUCT SUPPLY

2.1 **Purchase and Sale**. Pursuant to the terms and conditions of this Supply Agreement, Rigel (either itself or through its Affiliates or Third Party subcontractors) shall manufacture and supply the Product and its placebo (if applicable) to Kissei in such quantities as Kissei shall order pursuant to and in accordance with this Article 2, and Kissei shall purchase from Rigel all of Kissei's and its Affiliates' and Sublicensees' requirements for Products for development and commercialization in the Field in the Kissei Territory pursuant to and in accordance with the Collaboration and License Agreement. Kissei shall have the right to purchase the Product on a Batch or Drum basis subject to the Specifications to be agreed upon by the Parties. For clarity, Rigel may perform its obligations under

this Supply Agreement through one or more Third Party subcontractors, provided that Rigel remains responsible for the work allocated to, and payment to, such subcontractors as it selects, to the same extent it would if it had done such work itself. Notwithstanding the following Sections 2.2 and 2.3, the Parties agree that Kissei may amend Order Forecasts (as defined below) and Purchase Orders (as defined below) from time to time during the ** from the Effective Date with the prior mutual consent of the Parties via the JSC and Rigel shall supply the Product to Kissei in such agreed quantities.

2.2 Order Forecasts.

(a) Rolling Forecast. At least ** before the ** of each Calendar Quarter during the Term of this Supply Agreement, Kissei shall provide Rigel a rolling forecast of its monthly requirements for the quantity of Products to be used for (i) Development purposes for the following ** period commencing from such Calendar Quarter and (ii) Commercial use for the following ** period commencing from such Calendar Quarter ("**Order Forecast**"). For clarity, each Order Forecast shall itemize the applicable quantity (i.e., the unit of Drum or naked bottle, but not limited to such unit) of the Product and its placebo (if applicable) for each of Development and Commercial use. Each Order Forecast shall be made in good faith for budget and capacity planning purposes only and shall be non-binding on Kissei and Rigel, except as provided in Section 2.2(b). The Parties shall discuss and review the Order Forecast at each regularly scheduled meeting of the JSC established by the Parties under the Collaboration and License Agreement (or by a subcommittee established by the JSC to oversee the manufacture and supply of the Product). The Order Forecast will be in substantially the form attached hereto as **Exhibit B**.

(b) Binding Commitment. The ** of each Order Forecast shall constitute a binding commitment for Kissei to purchase, pursuant to Section 2.3(a), ** of the quantities of the Product ** specified therein and Kissei shall be required to order such quantities pursuant to Section 2.3(a). For clarity, the numbers set out in the following ** for the Development purpose and **for the Commercial use of the Order Forecast constitute the non-binding forecast of Kissei's expected requirements.

2.3 Purchase Orders; Delivery Terms.

(a) Purchase Orders. On or before the ** of each Calendar Quarter during the Term of this Supply Agreement, Kissei shall submit to Rigel a binding purchase order (a "**Purchase Order**") for the Product and its placebo (if applicable) to be delivered during the next Calendar Quarter of the most recent Order Forecast for Commercial use and/or Development use in quantities ** those set forth for such Calendar Quarter in the most recent Order Forecast. The Purchase Order will be in substantially the form attached hereto as **Exhibit C**. Rigel shall accept or reject each Purchase Order in writing within ** after its receipt of such Purchase Order; provided, however, that Rigel shall accept such Purchase Order if the quantities of the Product and its placebo (if applicable) ordered for each of Development and Commercial use in such Purchase Order are ** the quantities for such use set forth in the most recent Order Forecast, as applicable. The quantities of the Product and its placebo (if applicable) in the Purchase Order can only be changed if both Parties have agreed on such change in writing, provided that any changes are discussed and agreed upon at the JSC.

(b) Additional Quantities. In the event Kissei desires to obtain quantities of the Product and its placebo (if applicable) in a particular Calendar Quarter in excess of the quantities specified in the Order Forecast after such forecast became binding, Kissei shall notify Rigel in writing and the Parties will discuss in good faith whether Rigel may be able to supply Kissei with such additional quantities, provided that Rigel shall use Commercially Reasonable Efforts to accept such order for such additional quantities, and provided further that Kissei shall be solely responsible for any additional cost incurred in supplying such additional quantities. For clarity, Rigel shall not be obligated to accept any such order for additional quantities if accepting such order would result in or is reasonably likely to result in a Product and its placebo (if applicable) shortfall in the Rigel Territory.

(c) Delivery and Shipping Terms. Purchase Orders submitted for quantities of Product that are in accordance with Section 2.3(a) and/or Section 2.3(b) will be binding on both Parties after acceptance in writing by Rigel. The Purchase Order will specify delivery dates for such order to be delivered in such Calendar Quarter, but will in no event be a date sooner than ** the Purchase Order date. By way of example, a Purchase Order submitted on ** would specify the quantity of Product ordered for delivery in **, with a delivery date no sooner than **. Notwithstanding the foregoing, Rigel's delivery schedule under this Supply Agreement shall be subject to any change in the delivery schedule under the supply agreements between Rigel and its contract manufacturers. The Parties agree to discuss in good faith any adjustment of the minimum delivery time of ** from Purchase Order submission if a Party deems such an adjustment necessary, provided, however, that both Parties shall discuss in good faith Kissei's request

to deliver the Product and its placebo (if applicable) for Development purpose even on a date sooner than **. Rigel shall inform Kissei in advance of any such change. Rigel shall deliver all Product ** title and risk of loss shall pass from Rigel to Kissei upon the Product's being placed at the disposal of Kissei **. Rigel shall be responsible for obtaining all licenses or other authorizations for the exportation of such shipments and shall supply Kissei with the documentation required for filing or claiming credit or deduction for any applicable taxes and/or duties. Kissei shall be responsible for **, and shall be the importer of record and responsible for **, and shall be responsible for obtaining all distribution licenses for the Product. Notwithstanding the foregoing, Rigel shall **, and cooperates with Kissei on such shipment.

(d) Separate Contracts. Each Purchase Order will constitute a separate contract for the supply of the Product and its placebo (if applicable) on the terms of this Supply Agreement (and excluding all other terms and conditions including any set out or referred to in any Purchase Order). In the event of a conflict between a Purchase Order and the terms of this Supply Agreement, the terms of this Supply Agreement will govern.

2.4 Supply.

(a) Documentation. Rigel shall establish and maintain any necessary drug master files, standard operating procedures, protocols, and master batch records for the Manufacture of the Product and its placebo (if applicable). Rigel shall, in connection with each shipment of the Product to Kissei, provide to Kissei the certificate of compliance, certificate of analysis, completed batch records, and any other documentation as may be required in the Quality Agreement with respect to such shipment.

(b) Traceability. Rigel shall mark the Product and its placebo (if applicable) shipment supplied to Kissei with a lot number for the purposes of traceability. Kissei shall record the lot number of each Product and its placebo (if applicable) used for each Clinical Trial, promotion and marketing event, distributed to each patient in an expanded access program, or sold to each customer, and shall retain all such records for at least three **after the date of termination or expiration of this Supply Agreement to facilitate in the event of a Recall under Section 5.7 of the Collaboration and License Agreement.

(c) Form of Supply. Rigel shall supply Kissei with the Product and its placebo (if applicable) as outlined in the Specifications. . Kissei shall perform the Finish Manufacture of the Product and its placebo (if applicable), including final packaging and labeling, for Development uses. Kissei may perform the capsule appearance test with the appearance testing machine at its sole discretion and the Finish Manufacture of the Product, including final packaging and labeling, for Commercial uses. Kissei shall be responsible for ensuring that the Finished Product conforms with all Applicable Laws and Regulatory Approvals for each applicable jurisdiction within the Kissei Territory.

(d) Finished Product Release. Kissei (by itself or through its contract manufacturer) shall conduct release tests of the Finished Product, and the Parties will agree to a mechanism in the Quality Agreement for the shipment of test samples, such as samples for release testing of each Batch of the Product to Kissei for local release testing purposes.

(f) Product Shelf Life. The Product supplied by Rigel to Kissei hereunder shall have a remaining shelf life at the time of delivery to Kissei pursuant to this Agreement of **. In the event that the Product shelf life is extended to **, then the Product supplied by Rigel to Kissei hereunder shall have a remaining shelf life of **.

(g) Inventory Management; Safety Stock. Each Party shall manage its inventory in a manner that maximizes the remaining shelf life of its inventory. Kissei shall carry a reasonable quantity of inventory of the Finished Product, and Rigel shall carry a reasonable quantity of raw materials, including the Compound, which may be used in the event of an interruption to the supply chain. The quantity of such safety stock shall at least be sufficient to cover the quantity set forth in the Order Forecast for **. The Parties shall replace and replenish the safety stock continuously on a first to expire, first out basis. Each Party shall be responsible for the cost of maintaining its own safety stock.

2.5 Inspection and Acceptance.

(a) Non-Conforming Product.

(i) Kissei shall inspect all shipments of the Product promptly upon receipt, and shall notify Rigel in writing in reasonable detail within ** of receipt if Kissei is rejecting any Product that fails to conform to Rigel's warranties set forth in Sections 8.2(a) or 8.2(b). All Product not rejected within such ** period will be deemed accepted.

(ii) If Kissei notifies Rigel of any nonconformity of any Product in accordance with Section 2.5(a)(i), Rigel shall have the right to inspect the Product in question and Kissei shall cooperate with Rigel's inspection, including providing Rigel with samples of the Product in question for testing upon request. If Rigel agrees with such notice of nonconformity and that such nonconformity was not caused by occurrences after the delivery of the Product to Kissei, Rigel shall, at its discretion and expense, either: (A) replace such Product, ** as soon as reasonably practicable after receipt of notification of such nonconformity or (B) refund any portion of the applicable amount that has already been paid for such Product; provided, however, that if Rigel is required to make a payment to any contract manufacturer (or is not entitled to a refund from such contract manufacturer) in connection with any such non-conforming Product caused by Kissei or while under Kissei's control, Kissei shall be required to pay Rigel under this Supply Agreement with respect to such non-conforming Product unless and until Rigel is relieved of its payment obligation (or is refunded its payment) for such non-conforming Product under its agreements with such contract manufacturers.

(iii) In the event that Rigel disagrees with Kissei that the Product does not conform to Rigel's warranties set forth in Section 8.2(a) or 8.2(b), as applicable, or considers that the defect was caused by occurrences after the delivery of the Product to Kissei, it may require a sample of the allegedly nonconforming Product to be delivered to a mutually acceptable independent testing laboratory for testing or, in the case of a dispute concerning compliance with GMP, an independent consultant for evaluation. Except in the case of manifest error, the determination of the laboratory or consultant as to whether the Product is nonconforming will be final and binding on the Parties. The fees and expenses of such laboratory testing or consultant, as the case may be, shall be borne entirely by the Party against whom such laboratory's or consultant's determination is made. If, as the case may be, such determination is against Kissei, then such Product shall be deemed accepted by Kissei. If, as the case may be, such determination is against Rigel, then Rigel shall, subject to the instruction of Kissei, either refund any portion of the applicable amount that has already been paid by Kissei for such Product or replace such Product, at no additional cost to Kissei, as soon as reasonably possible, but in no event later than ** if replacement the Product stock is available, or if replacement the Product stock is unavailable at such time, as soon as reasonably practical after it becomes available; provided, however, that if Rigel is required to make a payment to any contract manufacturer (or is not entitled to a refund from such contract manufacturer) in connection with any such non-conforming Product caused by Kissei or while under Kissei's control, Kissei shall be required to pay Rigel under this Supply Agreement with respect to such non-conforming Product unless and until Rigel is relieved of its payment obligation (or is refunded its payment) for such non-conforming Product under its agreements with such contract manufacturers.

(iv) In the case of 2.5 (a) (ii) or (iii), Kissei shall have a right to request Rigel to supply the additional Product or its placebo (if applicable), so as not to cause any delays of the Development and Commercial activities, provided that any additional supply is discussed and agreed upon at the JSC.

(b) Sole Remedy. Notwithstanding anything to the contrary in this Supply Agreement, the remedy set forth in this Section 2.5 will be Kissei's sole and exclusive remedy and recourse with respect to the shortages that are not also nonconforming Product delivered to Kissei by Rigel hereunder.

(c) Damage after Delivery. Kissei shall bear the risk of damage to the Product after delivery to Kissei pursuant to Section 2.3(c). If the Product is damaged after delivery to Kissei pursuant to Section 2.3(c) and Kissei intends to order replacement Product, Kissei shall promptly notify Rigel of the damage and any orders for replacement Product, and Rigel may, at its sole discretion but in good faith, accept or reject all or a portion of the order for the replacement Product.

2.6 Quality Agreement. As soon as reasonably practicable after the Effective Date, the Parties shall agree to the terms and conditions of a quality agreement (the "**Quality Agreement**") setting forth in detail the quality assurance arrangements and procedures for the Manufacture of the Product, which Quality Agreement shall be incorporated herein by reference. For clarity, the Parties shall agree to the terms and conditions of (a) the Quality

Agreement for the Product for Development use as soon as reasonably practicable after the Effective Date, and (b) the Quality Agreement for the Product for Commercial uses, if different than the Quality Agreement specified in subsection (a), as soon as reasonably practicable after the first MAA for the Product is submitted in the Kissei Territory; provided that the Quality Agreement may be amended if mutually agreed by the Parties. To the extent that the terms of this Supply Agreement and those of the Quality Agreement are in conflict, the terms of this Supply Agreement shall control except with respect to quality issues, which shall be governed by the Quality Agreement. For clarity, if there are any financial terms in the Quality Agreement that are in conflict with this Supply Agreement, this Supply Agreement shall control with respect to such financial terms.

2.7 Backup Supplier. In the event that for a period of **, Rigel has failed to supply ** of the quantity of the Product **, Kissei shall have the right to manufacture the Compound and the Product by itself or a Third Party manufacturer in the Kissei Territory (a "**Backup Manufacturer**"). In preparation for manufacturing at the Backup Manufacturer, upon Kissei's reasonable request, Rigel shall ** transfer to Kissei the technology concerning the manufacture of the Compound and the Product after the Effective Date hereof. The costs and expenses associated with the engagement of the Backup Manufacturer, including the costs for transferring the Manufacturing process to such Backup Manufacturer, shall be borne **.

2.8 Allocation in the Event of Product Shortages.

(a) This Section 2.8 shall apply in the event that Rigel is unable to supply, with respect to a Calendar Quarter, ** (i) Product ordered by Kissei pursuant to Sections 2.2 and 2.3 for delivery in such Calendar Quarter, plus (ii) Product required by Rigel or its Affiliates or other licensees for their own use with respect to such Calendar Quarter (such event, a "**Shortfall**"). The purpose of these allocation rules is to permit Kissei (with respect to the Kissei Territory) and Rigel (with respect to the Rigel Territory) to independently make their respective long-term purchase decisions for the Product, with the benefits and risks of such purchase decisions to be allocated to Kissei or Rigel, as the case may be.

(b) If Rigel is unable to supply ** (i) Product ordered by Kissei pursuant to a Purchase Order plus (ii) Product required by Rigel or its Affiliates or other licensees for their own use, then the available Product in each Calendar Quarter in which a Shortfall occurs shall be **.

(c) The allocation rules set forth in this Section 2.8 shall restart for each Calendar Quarter, without any carryover of a Shortfall realized by either Kissei or Rigel in the prior Calendar Quarter.

(d) If Rigel determines that it will not be able to deliver the quantities of the Product specified in the Purchase Order on the requested delivery date, or Rigel is made aware of any future anticipated shortages, then Rigel shall promptly notify Kissei of such determination, and in any event, no later than ** following such determination. Such notification shall include the reasons for and the expected duration of Rigel's anticipated inability to deliver such quantities of the Product. Promptly thereafter, but in no event more than ** after such notification, the Parties shall discuss in good faith the matters set forth in such notification and begin good faith negotiations with respect to an alternative delivery schedule or alternative sourcing for such Product; provided that any such negotiations shall not relieve Rigel of its obligations hereunder.

2.9 Supply Contacts. Each Party shall designate one (1) qualified and experienced supply chain professional to serve as that Party's primary supply contact regarding the supply of the Product within this Supply Agreement ("**Supply Contacts**") and under the direction of the JSC. Each Party may replace its Supply Contact with an alternative representative at any time with prior written notice to the other Party. Supply Contacts shall be responsible for facilitating information exchange and discussion between the Parties regarding the supply of the Product under this Supply Agreement. Supply Contact shall have decision-making authority within the guidance and subject to the review and approval of the JSC. Each Party shall bear its own costs of its Supply Contact**.

ARTICLE 3
FINANCIALS

3.1 Price.

(a) Development Use. All the Product supplied by Rigel to Kissei for use for Development purposes shall be at the applicable price set forth in Section 7.1 of the Collaboration and License Agreement.

(b) Commercial Use. All the Product supplied by Rigel to Kissei for use for Commercial purposes shall be equal to the Transfer Price calculated in accordance with Section 8.4 of the Collaboration and License Agreement.

3.2 Invoice and Payment. Concurrently with delivery of Product to Kissei, Rigel shall submit to Kissei an invoice for payment, in U.S. Dollars, of the payment for such delivery, which invoice shall be prepared accordingly:

(a) for the Product and its placebo supplied for Development purposes, in accordance with Section 7.1 of the Collaboration and License Agreement,

(b) for the Product supplied for Commercial purposes during the Commercialization Term, in accordance with Section 8.4.2 of the Collaboration and License Agreement, and

(c) for the Product supplied for Commercial purposes during the Extended Commercialization Term, Kissei shall pay to Rigel a Transfer Price equal to **.

Kissei shall pay each invoice, in U.S. Dollars, within ** Kissei receives such invoice by wire transfer of immediately available funds into an account designated by Rigel. Financial audits shall be conducted in accordance with Section 9.4 of the Collaboration and License Agreement, and late payments shall bear interest as set forth in Section 9.5 of the Collaboration and License Agreement.

3.3 Other Manufacture and Test Related Costs. Kissei shall be responsible for the costs and expenses of Manufacture-related work including but not limited to any quality and stability test, that is performed by or on behalf of Rigel at Kissei's reasonable request, which costs and expenses are not included in the calculation of Cost of Goods, including internal costs, but excluding, for clarity, any costs and expenses specifically for capital investment that should generally be required by a pharmaceutical manufacturing facility. Within ** after the end of each Calendar Quarter during which such work has been performed by or on behalf of Rigel at Kissei's request, Rigel shall submit to Kissei a reasonably detailed invoice, in U.S. Dollars, setting forth the costs and expenses incurred by Rigel in connection with such work. Kissei shall pay to Rigel the amount invoiced, in U.S. Dollars, within ** after the end of the calendar month in which Kissei receives such invoice by wire transfer of immediately available funds into an account designated by Rigel. Late payments shall bear interest as set forth in Section 9.5 of the Collaboration and License Agreement.

3.4 Tax. Kissei shall pay any and all taxes (other than taxes based on Rigel 's income), duties, assessments, and other charges and expenses imposed by any Governmental Authority in connection with the supply and transfer of Product to Kissei. If a withholding or deduction obligation occurs, then the sum payable by Kissei (in respect of which such deduction or withholding is required to be made) shall be increased to the extent necessary to ensure that Rigel receives a sum equal to the sum which it would have received had no such withholding or deduction occurred.

ARTICLE 4
REGULATORY

4.1 Regulatory Inspections. Rigel shall cooperate with any inspection of its facilities by any Regulatory Authority overseeing the Manufacture of the Product for use in the Kissei Territory. Each Party shall notify the other Party of any such inspection and shall permit the other Party's representative to observe such inspection to the extent such inspection is scheduled at least ** in advance and such observation is permitted by Applicable Laws and any applicable agreement between Rigel and a Third Party (such as a contract manufacturing organization) in the event such facility is owned and/or operated by such Third Party.

4.2 GMP, Quality Assurance, and Other Audits . Kissei shall have the right to conduct GMP, quality assurance, and other audits (e.g., Environment, Health & Safety) pursuant to the terms and conditions of the Quality Agreement, but subject to any applicable agreement between Rigel and a Third Party (such as a contract manufacturing organization) in the event such facility is owned and/or operated by such Third Party. The Parties agree that the Statement of Facts document will be issued among the Parties and such Third Party to comply with the regulatory requirements in the Kissei Territory

4.3 Inquiries and Customer Complaints. Kissei shall comply with the Pharmacovigilance Agreement and Section 5.6 of the Collaboration and License Agreement with respect to all inquiries, complaints, and adverse events regarding the Products in the Kissei Territory.

4.4 Notification of Potential Recall; Recalls. Each Party will act in accordance with the notice requirements set forth in Section 5.9 of the Collaboration and License Agreement. In the event that any Recall with respect to a Product is the direct result of a breach of any warranty of Rigel set forth in Section 8.2 and is not the result of Kissei's, its Affiliates', or its sublicensees' Finish Manufacture, transportation, storage, marketing, use, sale, or distribution of the Product, then Rigel shall bear (and reimburse Kissei for) all of the costs and expenses of such recalled Product and the destruction of such recalled Product. To the extent that the reason for any Recall with respect to the Product hereunder is in part the direct result of the breach of any warranty of Rigel set forth in Section 8.2 and in part the result of Kissei's, its Affiliates', or its sublicensees' Finish Manufacture, transportation, storage, marketing, use, sale, or distribution of the Product, then the expenses of such Recall shall be allocated in an equitable manner between the Parties.

ARTICLE 5
CONFIDENTIALITY

5.1 Confidentiality. Any and all Information disclosed by a Party to the other Party under this Supply Agreement shall be deemed Confidential Information of such Party under the Collaboration and License Agreement and subject to the confidentiality provisions set forth in Article 12 of the Collaboration and License Agreement.

ARTICLE 6
INTELLECTUAL PROPERTY

6.1 Intellectual Property. Any and all inventions, whether patentable or not and including all intellectual property rights therein, generated by either Party in the course of conducting their activities under this Supply Agreement shall be deemed to be generated under the Collaboration and License Agreement and subject to the rights and obligations of the Parties as set forth therein.

ARTICLE 7
FORCE MAJEURE

7.1 Force Majeure. Notwithstanding anything to the contrary in this Supply Agreement, both Parties shall be excused from the performance of their obligations under this Supply Agreement to the extent that (a) force majeure prevents such performance or, with respect to Rigel's supply obligations pursuant to Article 2, prevents the combined supply of (i) Product specified in accepted orders placed by Kissei in accordance with Section 2.3(a) and (ii) Product required by Rigel and its Affiliates, and (b) the nonperforming Party promptly provides notice of the force majeure to the other Party. Such excuse shall continue so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Supply Agreement, force majeure shall include conditions beyond the reasonable control of the applicable Party, including an act of God, war, civil commotion, terrorist act, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm, or like catastrophe. Notwithstanding the foregoing, a Party will not be excused from making payments owed hereunder because of a force majeure affecting such Party. If a force majeure persists for more than **, then the Parties will discuss in good faith the modification of the Parties' obligations under this Supply Agreement in order to mitigate the delays caused by such force majeure.

ARTICLE 8
REPRESENTATIONS AND WARRANTIES

8.1 Mutual Representations and Warranties. Each Party represents and warrants to the other that, as of the Effective Date: (i) it is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation, and has full corporate or other power and authority to enter into this Supply Agreement and to carry out the provisions hereof, (ii) it is duly authorized to execute and deliver this Supply Agreement and to perform its obligations hereunder, and the person or persons executing this Supply Agreement on its behalf has been duly authorized to do so by all requisite corporate or partnership action, and (iii) this Supply Agreement is legally binding upon it, enforceable in accordance with its terms, and does not conflict with any agreement, instrument, or understanding, oral or written, to which it is a Party or by which it may be bound, nor violate any material law or regulation of any court, governmental body, or administrative or other agency having jurisdiction over it.

8.2 Product Warranties. Rigel represents and warrants to Kissei that:

(a) all Product supplied to Kissei pursuant to this Supply Agreement shall be Manufactured in conformity with GMPs;

(b) each Product supplied to Kissei pursuant to this Supply Agreement, at the time of shipment of such Product to Kissei pursuant to Section 2.3(c), shall conform to the applicable Specifications for such Product; and

(c) all Product supplied to Kissei pursuant to this Supply Agreement shall, at the time of shipment of such Product to Kissei pursuant to Section 2.3(c), be free and clear of all liens, security interests, and other encumbrances; provided, however, that Rigel shall retain a security interest in such Product until Kissei pays for it in full pursuant to Section 3.2 of this Supply Agreement and Section 8.5 of the Collaboration and License Agreement.

8.3 Disclaimers. EXCEPT AS EXPRESSLY STATED IN THIS SUPPLY AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, AND FITNESS FOR A PARTICULAR PURPOSE, ARE MADE OR GIVEN BY OR ON BEHALF A PARTY, AND ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

ARTICLE 9
INDEMNIFICATION

9.1 Indemnification by Rigel. Rigel hereby agrees to defend, indemnify, and hold harmless Kissei and its Affiliates and their respective directors, officers, employees, and agents (each, a "**Kissei Indemnitee**") from and against any and all liabilities, expenses, and losses including any product liability, personal injury, property damage, including reasonable legal expenses and attorneys' fees (collectively, "**Losses**"), to which any Kissei Indemnitee may become subject as a result of any claim, demand, action, or other proceeding by any Third Party to the extent such Losses arise out of or result from: (a) the negligence or willful misconduct of any Rigel Indemnitee, or (b) the breach by Rigel of any warranty, representation, covenant, or agreement made by Rigel in this Supply Agreement; except, in each case (a)-(b), to the extent such Losses arise out of any activities set forth in Section 9.2(a), (b), (c), or (d) for which Kissei is obligated to indemnify any Rigel Indemnitee(s) under Section 9.2.

9.2 Indemnification by Kissei. Kissei hereby agrees to defend, indemnify, and hold harmless Rigel, its Affiliates, and licensees and their respective directors, officers, employees, and agents (each, a "**Rigel Indemnitee**") from and against any and all Losses to which any Rigel Indemnitee may become subject as a result of any claim, demand, action, or other proceeding by any Third Party to the extent such Losses arise out of: (a) the negligence or willful misconduct of any Kissei Indemnitee, (b) the breach by Kissei of any warranty, representation, covenant, or agreement made by Kissei in this Supply Agreement, (c) the Finish Manufacture, export, import, storage, packaging, or labeling, by or on behalf of Kissei or its Affiliates or sublicensees, of any Product supplied by Rigel hereunder, or (d) the commercialization of any Product supplied by Rigel hereunder; except, in each case (a)-(d), to the extent such Losses arise out of any activities set forth in Section 9.1(a) or (b) for which Rigel is obligated to indemnify any Kissei Indemnitee(s) under Section 9.1.

9.3 Indemnification Procedures. A party that intends to claim indemnification under this Article 9 (the "**Indemnitee**") shall promptly notify the indemnifying Party (the " **Indemnitor**") in writing of any Third Party claim, demand, action, or other proceeding (each, a "**Claim**") in respect of which the Indemnitee intends to claim such indemnification, and the Indemnitor shall have sole control of the defense or settlement thereof. The Indemnitee may participate at its expense in the Indemnitor's defense of and settlement negotiations for any Claim with counsel of the Indemnitee's own choice. The indemnity arrangement in this Article 9 shall not apply to amounts paid in settlement of any action with respect to a Claim if such settlement is effected without the consent of the Indemnitor, which consent shall not be unreasonably withheld or delayed. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any action with respect to a Third Party Claim shall only relieve the Indemnitor of its indemnification obligations under this Article 9 if and to the extent the Indemnitor is actually prejudiced thereby. The Indemnitee shall cooperate fully with the Indemnitor and its legal representatives in the investigation of any action with respect to a Claim covered by this indemnification.

9.4 Insurance. Each Party, at its own expense, shall maintain insurance as set forth in Section 12.4 of

the Collaboration and License Agreement.

9.5 Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, LOST PROFITS, PUNITIVE, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS SUPPLY AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 9.5 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTIONS 9.1 OR 9.2, OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF CONFIDENTIALITY OBLIGATIONS IN ARTICLE 5. WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, RIGEL'S OBLIGATIONS AND LIABILITY IN CONNECTION WITH ITS SUPPLY OBLIGATIONS UNDER THIS SUPPLY AGREEMENT (INCLUDING IN CONNECTION WITH ANY SUPPLY SHORTAGE, DELAYS, AND QUALITY AND OTHER MATTERS AND RIGEL'S INDEMNIFICATION OBLIGATIONS TO KISSEI UNDER THIS SUPPLY AGREEMENT) SHALL BE LIMITED TO THE EXTENT OF THE REMEDIES ACTUALLY OBTAINED AND RECOVERED BY RIGEL FROM ITS CONTRACT MANUFACTURERS UNDER THE SUPPLY AGREEMENTS BETWEEN RIGEL AND THE APPLICABLE CONTRACT MANUFACTURER.

ARTICLE 10
TERM AND TERMINATION

10.1 Term. This Supply Agreement shall commence on the Effective Date and shall continue until terminated as provided in this Section 10.2 (the "**Term**").

10.2 Termination.

(a) Material Breach. A Party's material breach of this Supply Agreement will constitute such Party's material breach of the Collaboration and License Agreement, and each Party shall have the right to terminate this Supply Agreement and the Collaboration and License Agreement for the other Party's uncured material breach of this Supply Agreement as set forth in Section 13.2.1 of the Collaboration and License Agreement.

(b) Due to Early Termination of the Collaboration and License Agreement. This Supply Agreement shall automatically terminate upon termination of the Collaboration and License Agreement pursuant to Section 13.2 or 13.3 of the Collaboration and License Agreement.

(c) After the Commercialization Term. Either Party shall have the right to terminate this Supply Agreement, on a Product-by-Product and country-by-country basis, without cause upon ** prior written notice to the other Party so long as such termination becomes effective on or after the end of the Commercialization Term for such Product in such country.

10.3 Effects of Termination; Survival. Termination or expiration of this Supply Agreement shall not affect the rights or obligations of the Parties under this Supply Agreement that have accrued prior to the date of termination or expiration. Upon termination of this Supply Agreement for any reason: (a) Products Manufactured pursuant to Purchase Orders will be delivered on the scheduled delivery dates and Kissei shall pay Rigel not later than ** after the delivery date (provided, however, that Kissei makes advance payment prior to shipment in the event of termination due to payment default by Kissei); and (b) all costs of unused and unusable by Rigel raw materials, labels, and packaging incurred by Rigel shall be paid by Kissei in the event that Rigel terminates this Supply Agreement pursuant to Section 10.2(a) or that this Supply Agreement is terminated pursuant to Section 10.2(b) as a result of termination of the Collaboration and License Agreement by Kissei pursuant to Sections 13.3.1 or 13.3.2 of the Collaboration and License Agreement. Notwithstanding anything to the contrary, the following provisions shall survive any expiration or termination of this Supply Agreement: Sections 5 (Confidentiality), 6 (Intellectual Property), 9 (Indemnification), 10.3 (Effects of Termination; Survival), and 11 (General Provisions).

ARTICLE 11
GENERAL PROVISIONS

11.1 Governing Law; Dispute Resolution. This Supply Agreement, and all questions regarding the existence, validity, interpretation, breach, or performance of this Supply Agreement, shall be governed by, and construed and enforced in accordance with, the laws of the State of New York, United States, without reference to its conflicts of law principles. The application of the U.N. Convention on Contracts for the International Sale of Goods

(1980) is excluded. Any controversy or claim arising out of, relating to, or in connection with any provision of this Supply Agreement shall be resolved in accordance with Article 14 of the Collaboration and License Agreement.

11.2 Entire Agreement; Amendment. This Supply Agreement, including the Exhibits, together with the Collaboration and License Agreement, is both a final expression of the Parties' agreement and a complete and exclusive statement with respect to all of its terms. This Supply Agreement supersedes all prior and contemporaneous agreements and communications, whether oral, written, or otherwise, concerning any and all matters contained herein. This Supply Agreement may only be modified or supplemented in a writing expressly stated for such purpose and signed by the Parties to this Supply Agreement. No modification to this Supply Agreement will be effected by the acknowledgment or acceptance of any Purchase Order or shipping instruction forms or similar documents containing terms or conditions at variance with or in addition to those set forth herein.

11.3 Notices. Any notice to be given under this Supply Agreement must be in writing and delivered either in person, by (a) air mail (postage prepaid) requiring return receipt, (b) overnight courier, (c) facsimile confirmed thereafter by any of the foregoing, or (d) email to the Party to be notified at its address(es) given below, or at any address such Party may designate by prior written notice to the other in accordance with this Section 11.3. Notice shall be deemed sufficiently given for all purposes upon the earliest of: (i) the date of actual receipt, (ii) if air mailed, ** after the date of postmark, (iii) if delivered by overnight courier, the next day the overnight courier regularly makes deliveries, or (iv) if sent by facsimile or email, the date of confirmation of receipt if during the recipient's normal business hours, otherwise the next business day.

If to Kissei, notices must be addressed to:

Kissei Pharmaceutical Co., Ltd
1-8-9 Nihonbashi-Muromachi,
Chuo-ku, Tokyo 103-0022 Japan
Attention: **
Facsimile: **
Email: **

with a copy to
Kissei Pharmaceutical Co., Ltd.
19-48 Yoshino, Matsumoto-City
Nagano-prefecture, 399-8710 Japan
Attention: **
Facsimile: **
Email: **

If to Rigel, notices must be addressed to:

Rigel Pharmaceuticals, Inc.
611 Gateway Blvd., Suite 900
South San Francisco, CA 94080 USA
Attention: **
Email: **

11.4 Interpretation. The headings of clauses contained in this Supply Agreement preceding the text of the sections, subsections, and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Supply Agreement, or have any effect on its interpretation or construction. All references in this Supply Agreement to the singular shall include the plural where applicable. Unless otherwise specified, references in this Supply Agreement to any Article shall include all Sections, subsections, and paragraphs in such Article, references to any Section shall include all subsections and paragraphs in such Section, and references in this Supply Agreement to any subsection shall include all paragraphs in such subsection. The word "including" and similar words means including without limitation. The word "or" means "and/or" unless the context dictates otherwise because the subjects of the conjunction are, or are intended to be, mutually exclusive. The words "herein", "hereof", and "hereunder" and other words of similar import refer to this Supply Agreement as a whole and not to any particular Section or other subdivision. All references to days in this Supply Agreement mean calendar days, unless otherwise specified. Ambiguities and uncertainties in this Supply Agreement, if any, shall not be interpreted against either Party, irrespective of which Party may be deemed to have caused the ambiguity or uncertainty to exist. This

Supply Agreement has been prepared in the English language and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral, or other communications between the Parties regarding this Supply Agreement shall be in the English language.

11.5 Assignment. Except as expressly provided hereunder, neither this Supply Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred by either Party without the prior written consent of the other Party (which consent shall not be unreasonably withheld); provided, however, that either Party may assign or otherwise transfer this Agreement and its rights and obligations hereunder without the other Party's consent:

(a) in connection with the assignment of the Collaboration and License Agreement to a Third Party as set forth in Section 15.5 of the Collaboration and License Agreement; or

(b) to an Affiliate, provided that the assigning Party shall remain liable and responsible to the non-assigning Party hereto for the performance and observance of all such duties and obligations by such Affiliate.

The rights and obligations of the Parties under this Supply Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties specified above, and the name of a Party appearing herein will be deemed to include the name of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Section 11.4. Any assignment not in accordance with this Section 11.4 shall be null and void.

11.6 Performance by Affiliates. Each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Supply Agreement, and shall cause its Affiliates to comply with the provisions of this Supply Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Supply Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

11.7 Further Actions. Each Party agrees to execute, acknowledge, and deliver the Quality Agreement.

11.8 Compliance with Applicable Laws. Each Party shall comply in all material respects with all Applicable Laws, including, but not limited to, those concerning drugs, drug manufacture regulatory requirements, or exportation or importation of Products, including but not limited to proper declaration of dutiable values. Except as provided in Section 2.3(c), Kissei shall be responsible for obtaining all exportation and importation licenses or other authorizations.

11.9 Severability. If, for any reason, any part of this Supply Agreement is adjudicated invalid, unenforceable, or illegal by a court of competent jurisdiction, such adjudication shall not, to the extent feasible, affect or impair, in whole or in part, the validity, enforceability, or legality of any remaining portions of this Supply Agreement. All remaining portions shall remain in full force and effect as if the original Supply Agreement had been executed without the invalidated, unenforceable, or illegal part.

11.10 No Waiver. The failure of a Party to insist upon strict performance of any provision of this Supply Agreement or to exercise any right arising out of this Supply Agreement shall neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance. Any waiver by a Party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time and shall be signed by such Party.

11.11 Relationship Between the Parties. The Parties' relationship, as established by this Supply Agreement together with the Collaboration and License Agreement, is solely that of independent contractors. This Supply Agreement does not create any partnership, joint venture, or similar business relationship between the Parties. Neither Party is a legal representative of the other Party and neither Party can assume or create any obligation, representation, warranty, or guarantee, express or implied, on behalf of the other Party for any purpose whatsoever.

11.12 Counterparts; Electronic or Facsimile Signatures. This Supply Agreement may be executed in any number of counterparts, each of which shall be an original, but all of which together shall constitute one instrument. This Supply Agreement may be executed and delivered electronically or by facsimile and upon such delivery such electronic or facsimile signature will be deemed to have the same effect as if the original signature had been delivered to the other Party.

In Witness Whereof, the Parties hereto have caused this **Supply Agreement** to be executed and entered into by their duly authorized representatives as of the Effective Date.

Rigel Pharmaceuticals, Inc.	**Kissei Pharmaceutical Co. Ltd.**
By: /s/ Raul R. Rodriguez	By: /s/ Mutsuo Kanzawa
Name: Raul R. Rodriguez	Name: Mutsuo Kanzawa
Title: President and CEO	Title: Chairman and CEO

{Signature Page to Supply Agreement}

LIST OF EXHIBITS

Exhibit A: Compound

Exhibit B: Form of Order Forecast

Exhibit C: Form of Purchase Order

Exhibit A: Compound

Olutasidenib is an isocitrate dehydrogenase-1 (IDH1) inhibitor. The chemical name is (S)-5-((1-(6-chloro-2-oxo-1, 2-dihydroquinolin-3-yl)ethyl)amino)-1-methyl-6-oxo-1,6-dihydropyridine-2-carbonitrile. The chemical structure is:

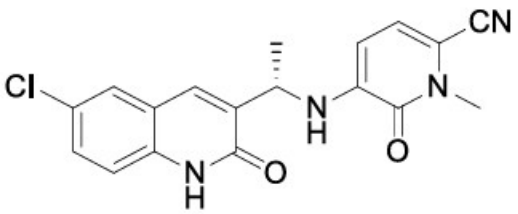

Exhibit B: Form of Order Forecast

**

**

Exhibit 10.3

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [**], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

4th Amendment to the COLLABORATION AND LICENSE AGREEMENT

This 4th Amendment to the COLLABORATION AND LICENSE AGREEMENT (the "Amendment") is made and entered into as of September 3, 2024, by and between RIGEL PHARMACEUTICALS, INC., a Delaware company having an address at 611 Gateway Blvd., Suite 900, South San Francisco, CA 94080, USA ("Rigel") and KISSEI PHARMACEUTICAL CO. LTD., a Japanese company having an address at 19-48 Yoshino, Matsumoto, Nagano 399-8710, Japan ("Kissei"). Rigel and Kissei may be referred to herein individually as a "Party" or collectively as the "Parties".

WHEREAS, Rigel and Kissei entered into and executed the COLLABORATION AND LICENSE AGREEMENT on Fostamatinib dated as of October 29, 2018 and the 1st Amendment to the COLLABORATION AND LICENSE AGREEMENT dated as of November 9, 2022 and 2nd Amendment to the COLLABORATION AND LICENSE AGREEMENT dated as of October 18, 2023 and 3rd Amendment to the COLLABORATION AND LICENSE AGREEMENT dated as of August 30, 2024 (the "License Agreement"); and

WHEREAS Rigel and Kissei have agreed to amend certain provisions of the License Agreement in relation to Transfer Price.

WHEREAS Rigel and Kissei have agreed that this new Transfer Price ** Drug Product **. For clarity, the Transfer Price ** Drug Product p**.

NOW, THEREFORE, pursuant to Section 16.2 of the License Agreement, and in consideration of the covenants and obligations contained herein and other valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

1. Section 8.5 of the Agreement is hereby deleted and replaced in its entirety with the following:

8.5 Transfer Price.

(a) Transfer Price During the Commercialization Term.

(i) In consideration for the quantity in units of the Drug Product provided by Rigel to Kissei for Commercial use ("**Units Provided**"), Kissei shall pay to Rigel a transfer price equal to the Units Provided ** (the "**Transfer Price**"). For clarity, the Parties will agree upon the ** for the initial order prior to the initial Purchase Order, and thereafter the Parties agree to review **. Additionally, Kissei shall pay to Rigel an amount to be calculated in accordance with the table below by multiplying the respective percentage rates set forth therein (the "**Transfer Price Rate**") less the Transfer Price for all Product sold by Kissei or on behalf of Kissei or its Affiliates or Sublicensees (excluding China, Hong Kong, Macau and Taiwan) during the Commercialization Term ("**True Up Transfer Price** "). The Transfer Price amount shall be paid within ** after the ** in which Kissei receives Rigel's invoice for such Units Provided. The True Up Transfer Price amount shall be calculated and paid in accordance with Section 8.5 (c) below. Notwithstanding anything to the contrary herein, Transfer Price for Kissei's Sublicensees licensed for territories in China, Hong Kong, Macau and Taiwan shall be the equal to Rigel's Cost of Goods. For the purposes of this Section 8.5, the term "Sublicensees" shall exclude Sublicensees licensed for territories in China, Hong Kong, Macau and Taiwan.

Annual Net Sales of all Products **	Transfer Price Rate
Portion less than or equal to $**	**%
Portion greater than $** and less than or equal to $**	**%
Portion greater than $**	**%

Annual Net Sales of all Products **	Transfer Price Rate
(Regardless of the sales scale)	**%

(ii) Notwithstanding the foregoing, on a country-by-country basis ** if ** a unit of Product exceeds an amount equal to ** for such unit of Product in such country or region (the "**Base Percent**"), the Transfer Price Rate set forth in Section 8.5(a)(i) for such unit of Product in such country or region shall be adjusted accordingly: for each ** the Base Percent, the Transfer Price Rate set forth in Section 8.5(a) (i) shall be increased by **, provided, however, that in no event shall the Transfer Price Rate exceed **. By way of example only, ** for the Product equals ** of the Gross Sales Price for such Product **, the Transfer Price Rate for such Product in such country shall be equal to ** for portions of Net Sales less than or equal to ** for portions of Net Sales greater than **, but less than **, and ** for portions of Net Sales greater than **.

(iii) The Transfer Price Rate in this Section 8.5(a) shall apply to the units of Products sold for the period during which such Transfer Price Rate(s) applies. If the Transfer Price for the Product ** for such Product falls below an amount equal to ** for such Product, the Parties shall discuss in good faith a modification in the Transfer Price Rate(s) for such Product **.

(b) True Up Transfer Price Payments During the Commercialization Term.

(i) ANS Calculation. Within ** after the end of each Calendar Quarter, Kissei shall calculate and report to Rigel in writing an estimate of the average per unit Net Sales for the Product in such Calendar Quarter, and within ** after the end of each Calendar Quarter, Kissei shall calculate and report to Rigel in writing the actual average per unit Net Sales for the Product in such Calendar Quarter (the "ANS") **. For ** (i) Kissei shall provide an estimate of ANS within ** after the end of each Calendar Quarter, and (ii) Kissei shall use Commercially Reasonable Effort to calculate and report to Rigel in writing the ANS in such Calendar Quarter within ** after the end of each Calendar Quarter but in no event later than ** after the end of each Calendar Quarter. The ANS shall be calculated by dividing the Net Sales for such Calendar Quarter in a country by the number of units of the Product sold by Kissei that constitutes the Net Sales for such period in such country.

(ii) True Up Calculation for Units Sold. Within ** after the end of each Calendar Quarter, Kissei shall calculate and report to Rigel in writing the estimated number of units sold of Units Provided, and within ** after the end of each Calendar Quarter, Kissei shall calculate and report to Rigel in writing the actual number of units sold of Units Provided in such Calendar Quarter (the "Units Sold") **. For ** (i) Kissei shall provide an estimate of Units Sold within ** after the end of each Calendar Quarter, and (ii) Kissei shall use Commercially Reasonable Effort to calculate and report to Rigel in writing the Units Sold within ** after the end of each Calendar Quarter but in no event later than ** after the end of each Calendar Quarter. The true up calculation for Units Sold (the "True Up on Units Sold") shall be as follows: the ANS multiplied by the Transfer Price Rate less the **, which will all be multiplied by the Units Sold [((ANS) x (Transfer Price Rate) – (**)) x (Units Sold) = True Up on Units Sold]. For clarity, the ** is calculated by **.

(iii) True Up Calculation for Units Lost. Within ** after the end of each Calendar Quarter, Kissei shall calculate and report to Rigel in writing the estimated number of units of Units Provided not sold, and within ** after the end of each Calendar Quarter, Kissei shall calculate and report to Rigel in writing the actual number of units of Units Provided not sold due to an identified loss in such Calendar Quarter (the "Units Lost") **. For ** (i) Kissei shall provide an estimate of Units Lost within **after the end of each Calendar Quarter, and (ii) Kissei shall use Commercially Reasonable Effort to calculate and report to Rigel in writing the Units Lost within ** after the end of each Calendar Quarter but in no event later than ** after the end of each Calendar Quarter. The true up calculation for Units Lost (the "True Up on Units Lost") shall be as follows: [(the number of Units Lost) x (Transfer Price Per Unit - Cost of Goods Per Unit) = True Up on Units Lost] . The Parties agree that the units of Product with ** constitute Units Lost **.

(iv) True-up Transfer Price Payment. The True-up Transfer Price payment amount will be calculated by [(True Up on Units Sold) – (True Up on Units Lost) = True Up Transfer Price payment]. If the amount of the True Up Transfer Price is a positive value, then Kissei will pay Rigel such amount within ** after Kissei receives Rigel's invoice. If the amount of the True Up Transfer Price is a negative value, then Rigel will credit Kissei such amount against future payments hereunder.

(v) Related Reporting. In connection with the foregoing subsections (ii) and (iii), within ** after the end of each Calendar Quarter during the Commercialization Term, Kissei shall provide Rigel with a report that details the lot number of Units Sold and Units Lost. Additionally, Kissei shall promptly provide Rigel with any other reports or information reasonably requested by Rigel.

(c) Transfer Price Adjustments During the Commercialization Term.

(i) During the Commercialization Term, if one or more Generic Products to a Product is sold in any country in the Kissei Territory for such Product in such country, and such Generic Products ** during such Calendar Quarter, the Transfer Price Rates provided in Section 8.5(a) for such Product shall be reduced in such country by ** for such Calendar Quarter.

(ii) During the Commercialization Term, if it is necessary for Kissei to obtain a license from a Third Party under any Patent in a particular country in the Kissei Territory in order to sell a Product in such country and Kissei obtains such a license, Kissei may deduct from the Transfer Price that would otherwise have been due pursuant to Section 8.5(a) with respect to Net Sales of such Product in such country in a particular Calendar Quarter an amount equal to ** paid by Kissei to such Third Party pursuant to such license on account of the sale of such Product in such country during such Calendar Quarter. For clarity, **.

(iii) Notwithstanding the foregoing, during any Calendar Quarter in the Commercialization Term for a Product in a country, the operation of subsection (i) and (ii) above, individually or in combination, shall not reduce by more than ** the Transfer Price that would otherwise have been due under Section 8.5(a) with respect to Net Sales of such Product in such country during such Calendar Quarter. Kissei shall not be permitted to carry forward to subsequent Calendar Quarters any amounts it was not able to credit as a result of this subsection (iii).

(d) Transfer Price During the Extended Commercialization Term . In consideration for the Drug Product provided by Rigel to Kissei for Commercial use, Kissei shall pay to Rigel a Transfer Price equal to ** for such Drug Product ** for all Product manufactured and delivered during the Extended Commercialization Term. For clarity, Kissei shall have the right to obtain other source(s) of supply for the Compound and Drug Product and to conclude a contract with Rigel's manufacturers directly after the Commercialization Term.

(e) Transfer Price Payments During the Extended Commercialization Term. The Transfer Price payable by Kissei to Rigel for each unit of Drug Product delivered to Kissei during the Extended Commercialization Term under Section 8.5(d) shall be due within ** after Kissei's receipt from Rigel of an invoice for such Drug Product. For clarity, such payments shall not be subject to any offsets or reductions whatsoever, including those set forth in Section 8.5(c).

2. Capitalized terms not otherwise defined herein shall have the same meaning as set forth in the License Agreement. All other provisions in the License Agreement that have not been changed by this Amendment shall remain in full force and effect.

3. This Amendment may be executed by the Parties individually or in any combination, in one or more counterparts, each of which shall be an original and all of which shall together constitute one and the same agreement. Signatures transmitted by facsimile transmission, by electronic mail in "portable document format" (".pdf") form, or by any other electronic means intended to preserve the original graphic and pictorial appearance of a document, shall have the same force and effect as physical execution and delivery of the paper document bearing the original signature.

IN WITNESS WHEREOF, the Parties hereto have caused this Amendment to be executed and entered into by their duly authorized representatives as of the date hereof.

RIGEL PHARMACEUTICALS, INC.

By: /s/ Raul R. Rodriguez
Name: Raul R. Rodriguez
Title: President and CEO

KISSEI PHARMACEUTICAL CO. LTD.

By: /s/ Mutsuo Kanzawa
Name: Mutsuo Kanzawa
Title: Chairman and CEO

3rd Amendment to the COLLABORATION AND LICENSE AGREEMENT

This 3rd Amendment to the COLLABORATION AND LICENSE AGREEMENT (the "Amendment") is made and entered into as of August 30, 2024, by and between RIGEL PHARMACEUTICALS, INC., a Delaware company having an address at 611 Gateway Blvd., Suite 900, South San Francisco, CA 94080, USA ("Rigel") and KISSEI PHARMACEUTICAL CO. LTD., a Japanese company having an address at 19-48 Yoshino, Matsumoto, Nagano 399-8710, Japan ("Kissei"). Rigel and Kissei may be referred to herein individually as a "Party" or collectively as the "Parties".

WHEREAS, Rigel and Kissei entered into and executed the COLLABORATION AND LICENSE AGREEMENT on Fostamatinib dated as of October 29, 2018 and the 1st Amendment to the COLLABORATION AND LICENSE AGREEMENT dated as of November 9, 2022 and 2nd Amendment to the COLLABORATION AND LICENSE AGREEMENT dated as of October 18, 2023 (the "License Agreement"); and

WHEREAS Rigel and Kissei have agreed to amend certain provisions of the License Agreement in relation to ** for China, Hong Kong, Macau and Taiwan.

NOW, THEREFORE, pursuant to Section 16.2 of the License Agreement, and in consideration of the covenants and obligations contained herein and other valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

1. Section 8.3 of the License Agreement is hereby deleted and replaced in its entirety with the following:

8.3 Development Milestone Payments.

(a) Development Milestones. Subject to the remainder of this Section 8.3, Kissei shall pay to Rigel the one-time, non-refundable, non-creditable payments set forth in the table below upon the achievement of the applicable milestone event, whether by or on behalf of Kissei or its Affiliates or Sublicensees (excluding China, Hong Kong, Macau and Taiwan).

Milestone Event	**Milestone Payment**		
	For 1st Indication Achieved	**For 2nd Indication Achieved**	**For 3rd Indication Achieved**
**	$**	$**	$**
**	$**	$**	$**
**	$**	$**	$**

For the application of the table above: (i) if ** is the ** Indication to achieve a milestone event, Kissei shall pay to Rigel the milestone payment for such milestone event set forth in the column for the ** Indication achieved, and for **, the milestone payment set forth in the column for the **Indication shall apply, unless such Indication is **, in which event the milestone payment set forth in the column for the ** Indication shall apply and the column for the ** Indication shall apply to achievement of the milestone event in a ** Indication; (ii) if ** is the ** Indication to achieve a milestone event, Kissei shall pay to Rigel the milestone payment for such milestone event set forth in the column for the ** Indication achieved, and for **, the milestone payment set forth in the column for the ** Indication shall apply, unless such Indication is **, in which event the milestone payment set forth in the column for the ** Indication shall apply and the column for the ** Indication shall apply to achievement of the

milestone event in a ** Indication; and (iii) if ** is the ** Indication to achieve a milestone event, Kissei shall pay to Rigel the milestone payment for such milestone event set forth in the column for the ** Indication achieved, and for **, the milestone payment set forth in the column for the ** Indication shall apply if such milestone payment for the ** Indication has not been made (i.e., **) or, the milestone payment set forth in the column for the ** Indication shall apply if such milestone payment for the ** Indication has previously been made. For clarity, each milestone payment above shall be paid not more than once for each Indication and overall for no more than three Indications under this Agreement, and the total amount payable by Kissei to Rigel pursuant to this Section 8.3(a) is **. By way of example only, **. By way of further example only, **. By way of further example only, **.

(b) Notice and Payment. Kissei shall notify Rigel in writing within ** after the achievement of any milestone set forth in this Section 8.3 by Kissei or its Affiliates or Sublicensees (excluding China, Hong Kong, Macau and Taiwan) and, in the case of Independent Work conducted by Rigel in the Kissei Territory, Rigel will notify Kissei in writing within ** after the achievement of any milestone set forth in this Section 8.3 by Rigel. Promptly following receipt of any such notice from Kissei, Rigel will issue an invoice for the applicable development milestone payment to Kissei. Kissei shall pay to Rigel the applicable development milestone payment within ** after the receipt of such invoice.

2. Section 8.5 of the Agreement is hereby deleted and replaced in its entirety with the following:

8.5 Transfer Price.

(a) Transfer Price During the Commercialization Term.

(i) In consideration for the Drug Product provided by Rigel to Kissei for Commercial use, Kissei shall pay to Rigel a provisional transfer price (the "**Transfer Price**") equal to the percentage rates set forth in the table below (the "**Transfer Price Rate**") for all Product provided to Kissei for sale by or on behalf of Kissei or its Affiliates or Sublicensees (excluding China, Hong Kong, Macau and Taiwan) during the Commercialization Term. Notwithstanding anything to the contrary herein, Transfer Price for Kissei's Sublicensees licensed for territories in China, Hong Kong, Macau and Taiwan shall be the equal to **. For the purposes of this Section 8.5, the term "Sublicensees" shall exclude Sublicensees licensed for territories in China, Hong Kong, Macau and Taiwan.

Annual Net Sales of all Products **	**Transfer Price Rate**
Portion less than or equal to $**	**%
Portion greater than $** and less than or equal to $**	**%
Portion greater than $**	**%

Annual Net Sales of all Products **	**Transfer Price Rate**
(Regardless of the sales scale)	**%

(ii) Notwithstanding the foregoing, on a country-by-country or region-by-region basis, if ** a unit of Product exceeds an amount equal to ** for such unit of Product in such country or region (the " **Base Percent**"), the Transfer Price Rate set forth in Section 8.5(a)(i) for such unit of Product in such country or region shall be adjusted accordingly: for ** Base Percent, the Transfer Price Rate set forth in Section 8.5(a)(i) shall be increased by **, provided, however, that in no event shall the Transfer Price Rate exceed **. By way of example only, ** for such Product in a particular country, the Transfer Price Rate for such Product in such country shall be

equal to ** for portions of Net Sales less than or equal to ** for portions of Net Sales greater than **, but less than **, and ** for portions of Net Sales greater than **. For clarity, the Transfer Price Rate in this Section 8.5(a) shall apply to the units of Products sold for the period during which such Transfer Price Rate(s) applies, regardless of when such Products are manufactured and/or supplied to Kissei. If, during the Commercialization Term, the Transfer Price for the Product ** for such Product falls below an amount equal to ** for such Product, the Parties shall discuss in good faith a modification in the Transfer Price Rate(s) for such Product **.

(b) Transfer Price During the Extended Commercialization Term. In consideration for the Drug Product provided by Rigel to Kissei for Commercial use, Kissei shall pay to Rigel a Transfer Price equal to ** for all Product manufactured for sale by or on behalf of Kissei or its Affiliates or Sublicensees during the Extended Commercialization Term. For clarity, Kissei shall have the right to obtain other source(s) of supply for the Compound and Drug Product and to conclude a contract with Rigel's manufacturers directly after the Commercialization Term.

(c) Transfer Price Payments During the Commercialization Term.

(i) Estimated Price. No later than ** the first Product in the first Indication in the Kissei Territory, Kissei shall calculate and report to Rigel its good-faith, estimated average per unit Net Sales price for the Product in the Kissei Territory (the "**ENS**") until the end of that Calendar Year. Thereafter, no later than ** before the beginning of each Calendar Year, Kissei shall calculate and report to Rigel the ENS for the Product in the Kissei Territory for such Calendar Year. The ENS shall be calculated and reported by Kissei on a country-by-country basis.

(ii) Initial Payment. For each unit of Drug Product delivered to Kissei in a Calendar Quarter during the Commercialization Term, Kissei shall pay to Rigel an amount equal to the Transfer Price Rate of the applicable ENS for Drug Product for such Calendar Quarter, which amount shall be paid within ** Kissei receives Rigel's invoice for such quantity of Drug Product.

(iii) Actual Price and True Up. Within ** after the end of each Calendar Quarter during the Commercialization Term, Kissei shall calculate and report to Rigel in writing the actual average per unit Net Sales price for the Product in the Kissei Territory in such Calendar Quarter (the "**ANS**") on a country-by-country basis. The ANS shall be calculated by dividing the Net Sales for such Calendar Quarter in a country by the number of units of Product sold by Kissei that constitutes the Net Sales for such period in such country. Within ** after Kissei's report of the ANS for a Calendar Quarter:

(1) if the ANS is greater than the ENS for a country, then Kissei shall pay to Rigel a true up payment equal to the applicable Transfer Price Rate multiplied by (ANS – ENS) for each unit of Drug Product ordered by Kissei and delivered by Rigel for Commercial use in such country during such Calendar Quarter; and

(2) if the ANS is less than the ENS for a country, then Rigel shall issue a credit to Kissei equal to the applicable Transfer Price Rate multiplied by (ENS – ANS) for each unit of such Drug Product ordered by Kissei and delivered by Rigel for Commercial use in such country during such Calendar Quarter.

(d) Transfer Price Adjustments During the Commercialization Term.

(i) During the Commercialization Term, if one or more Generic Products to a Product is sold in any country in the Kissei Territory for such Product in such country, and such Generic Products ** during such Calendar Quarter, the Transfer Price Rates provided in Section 8.5(a) for such Product shall be reduced in such country by ** for such Calendar Quarter.

(ii) During the Commercialization Term, if it is necessary for Kissei to obtain a license from a Third Party under any Patent in a particular country in the Kissei Territory in order to sell a Product in such country and Kissei obtains such a license, Kissei may deduct from the Transfer Price that would otherwise have been due pursuant to Section 8.5(a) with respect to Net Sales of such Product in such country in a particular Calendar

Quarter an amount equal to ** paid by Kissei to such Third Party pursuant to such license on account of the sale of such Product in such country during such Calendar Quarter. For clarity, **.

(iii) Notwithstanding the foregoing, during any Calendar Quarter in the Commercialization Term for a Product in a country, the operation of subsection (i) and (ii) above, individually or in combination, shall not reduce by more than ** the Transfer Price that would otherwise have been due under Section 8.5(a) with respect to Net Sales of such Product in such country during such Calendar Quarter. Kissei **.

(e) Transfer Price Payments During the Extended Commercialization Term. The Transfer Price payable by Kissei to Rigel for each unit of Drug Product delivered to Kissei during the Extended Commercialization Term under Section 8.5(b) shall be due within ** after Kissei's receipt from Rigel of an invoice for such Drug Product. For clarity, such payments shall not be subject to any offsets or reductions whatsoever, including those set forth in Section 8.5(d).

3. A new Section 8.6 of the License Agreement is hereby added as follows:

8.6 ** Sublicensees.

(a) China, Hong Kong, Macau and Taiwan. Notwithstanding anything to the contrary in this Agreement, Kissei will ** Kissei or its Affiliates by Kissei's Sublicensees licensed for territories in China, Hong Kong, Macau and Taiwan. For clarity, **.

(b) Notice and Payment. Kissei shall notify Rigel in writing within ** after receipt by Kissei or its Affiliates by Kissei's Sublicensees in China, Hong Kong, Macau and Taiwan of **. Promptly following receipt of any such notice from Kissei, Rigel will **. Kissei shall **.

4. Capitalized terms not otherwise defined herein shall have the same meaning as set forth in the License Agreement. All other provisions in the License Agreement that have not been changed by this Amendment shall remain in full force and effect.

5. This Amendment may be executed by the Parties individually or in any combination, in one or more counterparts, each of which shall be an original and all of which shall together constitute one and the same agreement. Signatures transmitted by facsimile transmission, by electronic mail in "portable document format" (".pdf") form, or by any other electronic means intended to preserve the original graphic and pictorial appearance of a document, shall have the same force and effect as physical execution and delivery of the paper document bearing the original signature.

IN WITNESS WHEREOF, the Parties hereto have caused this Amendment to be executed and entered into by their duly authorized representatives as of the date hereof.

RIGEL PHARMACEUTICALS, INC.	**KISSEI PHARMACEUTICAL CO. LTD.**
By: /s/ Raul R. Rodriguez	By: /s/ Mutsuo Kanzawa
Name: Raul R. Rodriguez	Name: Mutsuo Kanzawa
Title: President and CEO	Title: Chairman and CEO

2nd Amendment to the COLLABORATION AND LICENSE AGREEMENT

This 2nd Amendment to the COLLABORATION AND LICENSE AGREEMENT (the "Amendment") is made and entered into as of October 18th, 2023, by and between RIGEL PHARMACEUTICALS, INC., a Delaware company having an address at 611 Gateway Blvd., Suite 900, South San Francisco, CA 94080, USA ("Rigel") and KISSEI PHARMACEUTICAL CO. LTD., a Japanese company having an address at 19-48 Yoshino, Matsumoto, Nagano 399-8710, Japan ("Kissei"). Rigel and Kissei may be referred to herein individually as a "Party" or collectively as the "Parties".

WHEREAS, Rigel and Kissei entered into and executed the COLLABORATION AND LICENSE AGREEMENT on Fostamatinib dated as of October 29, 2018 (the "License Agreement") and the 1st Amendment to the COLLABORATION AND LICENSE AGREEMENT dated as of November 9, 2022; and

WHEREAS Rigel and Kissei have agreed to amend certain provisions of the License Agreement in relation to Taiwan among the Kissei Territory.

NOW, THEREFORE, pursuant to Section 16.2 of the License Agreement, and in consideration of the covenants and obligations contained herein and other valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

1. Section 4.8 (c) of the Agreement is hereby deleted and replaced in its entirety with the following

   "(c) **Sublicensing Requirements**. If by the ** of the Effective Date Kissei has accomplished none of the following in China or Korea, and by the by the ** of the Effective Date Kissei has accomplished none of the following in Taiwan: (i) ** for the Product, or (ii) ** for the Product, or (iii) ** the Product, then Rigel shall inform Kissei of its decision to regain the right to the Product in the applicable country or region and the Parties shall promptly, and in any event within ** after Rigel so informs Kissei, confirm in writing that such country or region shall no longer be included in the Kissei Territory under this Agreement and shall become part of the Rigel Territory. For clarity, if the Parties fail to so confirm in writing that any such country or region is no longer included in the Kissei Territory within such ** period, such country or region shall automatically be deemed part of the Rigel Territory and excluded from the Kissei Territory upon the expiration of such ** period. In addition, prior to Kissei's **, if Rigel or Kissei receives a sublicensing request under the licenses granted to Kissei under this Agreement to Develop and Commercialize the Product in such country, Kissei shall use good faith efforts to negotiate a sublicense agreement with the requesting party on commercially reasonable terms and in accordance with Section 2.2."

2. Capitalized terms not otherwise defined herein shall have the same meaning as set forth in the License Agreement. All other provisions in the License Agreement that have not been changed by this Amendment shall remain in full force and effect.

3. This Amendment may be executed by the Parties individually or in any combination, in one or more counterparts, each of which shall be an original and all of which shall together constitute one and the same agreement. Signatures transmitted by facsimile transmission, by electronic mail in "portable document format" (".pdf") form, or by any other electronic means intended to preserve the original graphic and pictorial appearance of a document, shall have the same force and effect as physical execution and delivery of the paper document bearing the original signature.

IN WITNESS WHEREOF, the Parties hereto have caused this Amendment to be executed and entered into by their duly authorized representatives as of the date hereof.

RIGEL PHARMACEUTICALS, INC.	**KISSEI PHARMACEUTICAL CO. LTD.**
By: /s/ Raul R. Rodriguez	By: /s/ Mutsuo Kanzawa
Name: Raul R. Rodriguez	Name: Mutsuo Kanzawa
Title: President and CEO	Title: Chairman and CEO

1st Amendment to the COLLABORATION AND LICENSE AGREEMENT

This 1st Amendment to the COLLABORATION AND LICENSE AGREEMENT (the "Amendment") is made and entered into as of November 9th, 2022, by and between RIGEL PHARMACEUTICALS, INC., a Delaware company having an address at 1180 Veterans Blvd., South San Francisco, CA 94080, USA ("Rigel") and KISSEI PHARMACEUTICAL CO. LTD., a Japanese company having an address at 19-48 Yoshino, Matsumoto, Nagano 399-8710, Japan ("Kissei"). Rigel and Kissei may be referred to herein individually as a "Party" or collectively as the "Parties".

WHEREAS, Rigel and Kissei entered into and executed the COLLABORATION AND LICENSE AGREEMENT on Fostamatinib dated as of October 29, 2018 (the "License Agreement"); and

WHEREAS Rigel and Kissei have agreed to amend certain provisions of the License Agreement in relation to Taiwan among the Kissei Territory.

NOW, THEREFORE, pursuant to Section 16.2 of the License Agreement, and in consideration of the covenants and obligations contained herein and other valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

1. Section 1.32 of the Agreement is hereby deleted and replaced in its entirety with the following:

   "Drug Product" means the Compound manufactured into unit doses and provided in bright stock (unlabeled bottles) or as bulk tablets.

2. Section 10.1(b)(ii) of the Agreement is hereby deleted and replaced in its entirety with the following :

   All data, Inventions, and Patents claiming such Inventions that relate to the composition, manufacture, or use of any Compound, or any improvement of any such composition, manufacture, or use, including in combination with other agents or components, together with all intellectual property rights therein, shall be deemed "Compound Inventions". To the extent that any Compound Invention is made or acquired from a Sublicensee by Kissei, whether solely or jointly with Rigel, such Compound Invention shall be included in the license granted to Rigel by Kissei under Section 2.4, without additional consideration. Effective only upon the later of the expiration of the Commercialization Term or the expiration or termination of this Agreement: (A) Kissei hereby assigns to Rigel its rights, title, and interest in and to all Compound Inventions, and (B) solely in the event that the Commercialization Term expires, Rigel hereby grants to Kissei a fully-paid, royalty-free, perpetual, irrevocable, exclusive license under such Compound Inventions assigned by Kissei to Rigel for Kissei to use, sell, offer for sale, import, and otherwise Commercialize the Products in the Field in the Kissei Territory.

3. Section 4.8 (c) of the Agreement is hereby deleted and replaced in its entirety with the following

   "(c) **Sublicensing Requirements**. If by the ** of the Effective Date Kissei has accomplished none of the following in China or Korea, and by the by the ** of the Effective Date Kissei has accomplished none of the following in Taiwan: (i) ** for the Product, or (ii) ** for the Product, or (iii) ** the Product, then Rigel shall inform Kissei of its decision to regain the right to the Product in the applicable country or region and the Parties shall promptly, and in any event within ** after Rigel so informs Kissei, confirm in writing that such country or region shall no longer be included in the Kissei Territory under this Agreement and shall become part of the Rigel Territory. For clarity, if the Parties fail to so confirm in writing that any such country or region is no longer included in the Kissei Territory within such ** period, such country or region shall automatically be deemed part of the Rigel Territory and excluded from the Kissei Territory upon the expiration of such ** period. In addition, prior to Kissei's **, if Rigel or Kissei receives a sublicensing request under the licenses granted to Kissei under this Agreement to Develop and Commercialize the Product in such country, Kissei shall use good faith efforts to negotiate a sublicense agreement with the requesting party on commercially reasonable terms and in accordance with Section 2.2."

4. Capitalized terms not otherwise defined herein shall have the same meaning as set forth in the License Agreement. All other provisions in the License Agreement that have not been changed by this Amendment shall remain in full force and effect.

5. This Amendment may be executed by the Parties individually or in any combination, in one or more counterparts, each of which shall be an original and all of which shall together constitute one and the same agreement. Signatures transmitted by facsimile transmission, by electronic mail in "portable document format" (".pdf") form, or by any other electronic means intended to preserve the original graphic and pictorial appearance of a document, shall have the same force and effect as physical execution and delivery of the paper document bearing the original signature.

IN WITNESS WHEREOF, the Parties hereto have caused this Amendment to be executed and entered into by their duly authorized representatives as of the date hereof.

RIGEL PHARMACEUTICALS, INC.	**KISSEI PHARMACEUTICAL CO. LTD.**
By: /s/ Raul R. Rodriguez	By: /s/ Mutsuo Kanzawa
Name: Raul R. Rodriguez	Name: Mutsuo Kanzawa
Title: President and CEO	Title: Chairman and CEO

Exhibit 31.1

CERTIFICATION

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 7, 2024

/s/ RAUL R. RODRIGUEZ

Raul R. Rodriguez
Chief Executive Officer

Exhibit 31.2

CERTIFICATION

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 7, 2024

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

Exhibit 32.1

CERTIFICATIONS OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

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, 2024, 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 7, 2024.

/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.