

RIGEL PHARMACEUTICALS INC

Form 10-Q

November 03, 2009

[Table of Contents](#)

## **UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**FORM 10-Q**

**(Mark One)**

x

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

**FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2009**

**OR**

o

**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.**

Edgar Filing: RIGEL PHARMACEUTICALS INC - Form 10-Q

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of incorporation or organization)

**94-3248524**  
(I.R.S. Employer Identification No.)

**1180 Veterans Blvd.**  
**South San Francisco, CA**  
(Address of principal executive offices)

**94080**  
(Zip Code)

**(650) 624-1100**

(Registrant's telephone number, including area code)

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes  No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer   
(Do not check if a smaller reporting company)

Smaller reporting company

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

As of October 30, 2009, there were 51,821,947 shares of the registrant's common stock outstanding.

Table of Contents

**RIGEL PHARMACEUTICALS, INC.**  
**QUARTERLY REPORT ON FORM 10-Q**  
**FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2009**





**INDEX**



	<b>Page</b>
<b><u>PART I</u></b>	
<b><u>FINANCIAL INFORMATION</u></b>	
<b><u>Item 1.</u></b>	3
<u>Condensed Financial Statements</u>	3
<u>Condensed Balance Sheets – September 30, 2009 (Unaudited) and December 31, 2008</u>	3
<u>Condensed Statements of Operations (Unaudited) – three and nine months ended September 30, 2009 and 2008</u>	4
<u>Condensed Statements of Cash Flows (Unaudited) – nine months ended September 30, 2009 and 2008</u>	5
<u>Notes to Condensed Financial Statements (Unaudited)</u>	6
<u>Report of Independent Registered Public Accounting Firm</u>	14
<b><u>Item 2.</u></b>	15
<u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	
<b><u>Item 3.</u></b>	27
<u>Quantitative and Qualitative Disclosures About Market Risk</u>	
<b><u>Item 4.</u></b>	27
<u>Controls and Procedures</u>	
<b><u>PART II</u></b>	28
<b><u>OTHER INFORMATION</u></b>	
<b><u>Item 1.</u></b>	28
<u>Legal Proceedings</u>	
<b><u>Item 1A.</u></b>	28
<u>Risk Factors</u>	
<b><u>Item 6.</u></b>	40
<u>Exhibits</u>	
<b><u>Signatures</u></b>	41

Table of Contents**PART I. FINANCIAL INFORMATION****Item 1. Condensed Financial Statements****RIGEL PHARMACEUTICALS, INC.****CONDENSED BALANCE SHEETS****(In thousands, except share and per share amounts)**

	<b>September 30, 2009 (unaudited)</b>	<b>December 31, 2008 (1)</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 94,745	\$ 46,005
Available-for-sale securities	61,333	88,472
Prepaid expenses and other current assets	3,066	3,610
Total current assets	159,144	138,087
Property and equipment, net	2,605	3,567
Other assets	2,546	2,204
	\$ 164,295	\$ 143,858
<b>Liabilities and stockholders equity</b>		
Current liabilities:		
Accounts payable	\$ 3,504	\$ 5,984
Accrued compensation	3,844	1,625
Other accrued liabilities	11,848	12,029
Capital lease obligations	1,114	1,339
Deferred rent		3,174
Total current liabilities	20,310	24,151
Long-term portion of capital lease obligations	1,155	2,053
Long-term portion of deferred rent	12,360	13,311
Other long-term liabilities	162	178
Commitments and contingencies		
Stockholders equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized; none issued and outstanding as of September 30, 2009 and December 31, 2008		
Common stock, \$0.001 par value; 100,000,000 shares authorized; 51,821,947 and 36,646,397 shares issued and outstanding as of September 30, 2009 and December 31, 2008, respectively	52	37
Additional paid-in capital	718,469	605,509
Accumulated other comprehensive income	18	396
Accumulated deficit	(588,231)	(501,777)
Total stockholders equity	130,308	104,165
	\$ 164,295	\$ 143,858

---

(1) The balance sheet at December 31, 2008 has been derived from the audited financial statements at that date included in Rigel's Annual Report on Form 10-K for the year ended December 31, 2008.

See Accompanying Notes.

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

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>
Contract revenues	\$	\$	\$	\$
Costs and expenses:				
Research and development	21,082	31,232	70,568	81,268
General and administrative	5,573	7,450	15,226	21,436
Restructuring charges			1,141	
	26,655	38,682	86,935	102,704
Loss from operations	(26,655)	(38,682)	(86,935)	(102,704)
Interest income	48	1,034	554	3,853
Interest expense	(44)	(43)	(166)	(131)
Loss before income taxes	(26,651)	(37,691)	(86,547)	(98,982)
Income tax benefit			93	
Net loss	\$ (26,651)	\$ (37,691)	\$ (86,454)	\$ (98,982)
Net loss per share, basic and diluted	\$ (0.70)	\$ (1.03)	\$ (2.32)	\$ (2.76)
Weighted average shares used in computing net loss per share, basic and diluted	38,135	36,581	37,185	35,837

See Accompanying Notes.

Table of Contents**RIGEL PHARMACEUTICALS, INC.****CONDENSED STATEMENTS OF CASH FLOWS****(In thousands)****(unaudited)**

	<b>Nine Months Ended September 30,</b>	
	<b>2009</b>	<b>2008</b>
<b>Operating activities</b>		
Net loss	\$ (86,454)	\$ (98,982)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,057	1,064
Stock-based compensation expense	9,657	17,801
Changes in assets and liabilities:		
Prepaid expenses and other current assets	544	(203)
Other assets	274	115
Accounts payable	(2,480)	588
Accrued compensation	2,219	(3,182)
Other accrued liabilities	(181)	6,927
Deferred rent and other long-term liabilities	(4,141)	(506)
Net cash used in operating activities	(79,505)	(76,378)
<b>Investing activities</b>		
Purchases of available-for-sale securities	(82,871)	(170,146)
Maturities of available-for-sale securities	101,440	131,089
Sale of available-for-sale securities	8,192	
Capital expenditures	(95)	(1,759)
Net cash provided by (used in) investing activities	26,666	(40,816)
<b>Financing activities</b>		
Proceeds from capital lease financings		1,363
Payments on capital lease obligations	(1,123)	(903)
Net proceeds from issuances of common stock	102,702	129,949
Net cash provided by financing activities	101,579	130,409
Net increase in cash and cash equivalents	48,740	13,215
Cash and cash equivalents at beginning of period	46,005	44,503
Cash and cash equivalents at end of period	\$ 94,745	\$ 57,718
<b>Supplemental disclosure of cash flow information</b>		
Interest paid	\$ 142	\$ 129
<b>Schedule of non cash transactions</b>		
Issuance of warrant with lease amendment	\$ 616	\$

See Accompanying Notes.

Table of Contents

**Rigel Pharmaceuticals, Inc.**



**Notes to Condensed Financial Statements**

**(unaudited)**



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

## 1. Nature of Operations

We were incorporated in the state of Delaware on June 14, 1996. We are engaged in the discovery and development of novel, small-molecule drugs for the treatment of inflammatory/autoimmune diseases, as well as for certain cancers and metabolic diseases.

## 2. Basis of Presentation

Our accompanying unaudited condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP, for interim financial information and pursuant to the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and notes required by U.S. GAAP for complete financial statements. These unaudited condensed financial statements include all 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. The balance sheet at December 31, 2008 has been derived from audited financial statements at that date, but does not include all disclosures required by U.S. GAAP for complete financial statements. Because all of the disclosures required by U.S. GAAP for complete financial statements are not included herein, these interim unaudited condensed financial statements and the notes accompanying them should be read in conjunction with our audited financial statements and the notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2008.

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

In accordance with Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic No. 855, *Subsequent Events*, we evaluated subsequent events for recognition or disclosure through November 3, 2009, the date our accompanying condensed financial statements were issued.

## 3. Recent Accounting Pronouncements

In October 2009, the FASB issued Accounting Standards Update, or ASU, No. 2009-13 (formerly Emerging Issues Task Force, or EITF, No. 08-1) on ASC Topic No. 605 for revenue recognition related to multiple-deliverable revenue arrangements. The ASU provides amendments to the existing criteria for separating consideration in multiple-deliverable arrangements. The amendments establish a selling price hierarchy for determining the selling price of a deliverable, eliminate the residual method of allocation of arrangement consideration to all deliverables and require the use of the relative selling price method in allocation of arrangement consideration to all deliverables, require the determination of the best estimate of a selling price in a consistent manner, and significantly expand the disclosures related to the multiple-deliverable revenue arrangements. The amendments will be effective in fiscal years beginning on or after June 15, 2010, and early adoption is permitted. We are currently evaluating the impact on our financial statements of adopting these amendments to ASC Topic No. 605 and cannot estimate the impact of adoption at this time.

## Edgar Filing: RIGEL PHARMACEUTICALS INC - Form 10-Q

On July 1, 2009, the FASB launched the FASB Accounting Standards Codification<sup>TM</sup>, or the Codification, as the single source of authoritative U.S. GAAP recognized by the FASB. The Codification reorganizes various U.S. GAAP pronouncements into accounting topics and displays them using a consistent structure. All existing accounting standards documents are superseded as described in SFAS No. 168, *The FASB Accounting Standards Codification<sup>TM</sup> and the Hierarchy of Generally Accepted Accounting Principles* which is now part of ASC Topic No. 105. All of the contents of the Codification carry the same level of authority, effectively superseding SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*, which identified and ranked the sources of accounting principles and the framework for selecting the principles used in preparing the financial statements in conformity with U.S. GAAP. Also included in the Codification, as a reference for public companies, are rules and interpretive releases of the U.S. Securities and Exchange Commission, or the SEC, under authority of federal securities laws which are also sources of authoritative U.S. GAAP for SEC registrants. The Codification is effective for interim and annual periods ending after September 15, 2009. We adopted SFAS No. 168 on July 1, 2009 and concluded it had no material impact on our financial statements other than changing the way specific accounting standards are referenced in our financial statements.

Table of Contents

In September 2006, the FASB issued SFAS, No. 157, *Fair Value Measurements*, or SFAS No. 157, which now forms part of ASC Topic No. 820. This standard defines fair value, establishes a framework for measuring fair value under U.S. GAAP, and expands disclosures about fair value measurements. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, except that under FASB Staff Position, or FSP 157-2, *Effective Date of FASB Statement No. 157*, which now forms part of ASC Topic No. 820, companies are allowed to delay the effective date of SFAS No. 157 for non-financial assets and non-financial liabilities that are not recognized or disclosed at fair value on a recurring basis until fiscal years beginning after November 15, 2008. In October 2008, FSP 157-3, *Determining the Fair Value of a Financial Asset When the Market for that Asset is Not Active*, or FSP 157-3, which now forms part of ASC Subtopic No. 820-10, was issued and effective upon issuance, including prior periods for which financial statements have not been issued. FSP 157-3 clarified the application of SFAS No. 157 in a market that is not active. Effective January 1, 2008, we adopted the provisions of SFAS No. 157 for all financial assets and liabilities. Effective January 1, 2009, we adopted SFAS No. 157 for non-financial assets and liabilities. There was no material impact on our financial statements from the adoption of SFAS No. 157 for our financial or non-financial assets and liabilities.

**4. Basic and Diluted Net Loss Per Share**

Basic and diluted net loss per share was computed by dividing the net loss for the period by the weighted average number of shares of common stock outstanding during the period. The calculation of diluted net loss per share excluded shares of potential common stock, consisting of stock options and warrants, because their effect would have been anti-dilutive.

**5. Stock Award Plans**

Total stock-based compensation expense related to all of our stock-based awards that we recognized was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Research and development	\$ 2,356	\$ 3,035	\$ 6,309	\$ 9,229
General and administrative	1,176	3,001	3,226	8,572
Restructuring charges			122	
Total stock-based compensation expense	\$ 3,532	\$ 6,036	\$ 9,657	\$ 17,801

In February 2009, we announced that we cut our research programs in virology and oncology as well as terminated certain related development and administrative staff, which resulted in the dismissal of 36 employees, or approximately 20% of our workforce. This measure was intended to maintain our emphasis on our active preclinical and clinical programs, while conserving our resources. As part of a package we offered the terminated employees, we extended the date the terminated employees had to exercise their vested options to December 31, 2009 rather than 90 days from the termination date as is typically required under our equity incentive plan. We recorded \$122,000 of non-cash stock-based compensation expense related to this modification in the first quarter of 2009.

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

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

- Volatility We estimated volatility using the historical share price performance over the expected life of the option up to the point where we have historical market data. We also considered other factors, such as implied volatility, our current clinical trials and other company activities that may affect the volatility of our stock in the future. We determined that at this time historical volatility is more indicative of our expected future stock performance than implied volatility.

Table of Contents

- Expected term** We worked with various historical data to determine the applicable expected term for each option group. This data include: (1) for exercised options, the term of the options from option grant date to exercise date; (2) for cancelled options, the term of the options from option grant date to cancellation date, excluding unvested option forfeitures; and (3) for options that remained outstanding at the balance sheet date, the term of the options from option grant date to the end of the reporting period and the estimated remaining term of the options. The consideration and calculation of the above data gave us reasonable estimates of the expected term for each option group. We also considered the vesting schedules of the options granted and factors surrounding exercise behavior of the option groups, our current market price and company activity that may affect our market price. In addition, we considered the optionee type (i.e., officers and directors, all other employees and consultants) and other factors that may affect the expected term of the option. For options granted to consultants, we use the contractual term of the option, which is generally ten years, for the initial valuation of the option and the remaining contractual term of the option for the succeeding periods.
- Risk-free interest rate** The risk-free interest rate is based on U.S. Treasury constant maturity rates with similar terms to the expected term of the options for each option group.
- Forfeiture rate** We estimated the forfeiture rate using our historical experience with pre-vesting options. We review our forfeiture rates each quarter and make changes as factors affecting our forfeiture rate calculations and assumptions change.
- Dividend yield** The expected dividend yield is 0% as we have not paid and do not expect to pay dividends.

The following table summarizes the weighted-average assumptions relating to options granted pursuant to our equity incentive plans for the three and nine months ended September 30, 2009 and 2008:

	<b>Equity Incentive Plans Three Months Ended September 30,</b>		<b>Equity Incentive Plans Nine Months Ended September 30,</b>	
	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>
Risk-free interest rate	2.5%	3.1%	1.8%	2.8%
Expected term (in years)	4.0	4.0	4.4	4.5
Dividend yield	0.0%	0.0%	0.0%	0.0%
Expected volatility	103.5%	92.1%	98.4%	93.0%

Options are priced at the market price of our common stock on the date immediately preceding the date of grant, become exercisable at varying dates and generally expire ten years from the date of grant. We granted options to purchase 2,066,708 shares of common stock during the nine months ended September 30, 2009, with a grant-date weighted average fair value of \$4.65 per share. We granted options to purchase 1,528,180 shares of common stock during the nine months ended September 30, 2008, with a grant-date weighted average fair value of \$18.03 per share. As of September 30, 2009, there was approximately \$11.9 million of total unrecognized stock-based compensation cost, net of estimated forfeitures, related to unvested options granted under our equity incentive plans. At September 30, 2009, 2,673,643 shares of common stock were available for future grant under our equity incentive plans and options to purchase 129,839 shares were exercised during the nine months ended September 30, 2009.



*Employee Stock Purchase Plan (ESPP)*

The fair value of awards granted under our ESPP is estimated on the date of grant using the Black-Scholes option pricing model, which uses weighted-average assumptions. Our ESPP provides for a twenty-four month offering period comprised of four six-month purchase periods with a look-back option. A look-back option is a provision in our ESPP 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 ESPP also includes a feature that provides for a new offering period to begin when the fair market value of our common stock on any purchase date during an offering period falls below the fair market value of our common stock on the first day of such offering period. This feature is called a reset. Participants are automatically enrolled in the new offering period. We had a reset on January 2, 2009 because the fair market value of our stock on December 31, 2008 was lower than the fair market value of our stock on July 1, 2008, the first day of the offering period. We applied modification accounting in accordance with ASC Topic No. 718, *Stock Compensation*, to determine the incremental fair value associated with this ESPP reset and recognized the related stock-based compensation expense according to the FASB ASC Subtopic No. 718-50, *Employee Share Purchase Plan*. The total incremental fair value for this ESPP reset was \$1,443,848, and is being recognized over the new twenty-four month offering period.

Table of Contents

As of September 30, 2009, there were approximately 1,314,220 shares reserved for future issuance under the ESPP and 95,711 shares were purchased under the ESPP during the nine months ended September 30, 2009. The following table summarizes the weighted-average assumptions related to our ESPP for the nine months ended September 30, 2009 and 2008. Expected volatilities for our ESPP are based on the historical volatility of our stock. Expected term represents the weighted average of the purchase periods within the offering period. The risk-free interest rate for periods within the expected term is based on U.S. Treasury constant maturity rates.

	Employee Stock Purchase Plan Nine Months Ended September 30,	
	2009	2008
Risk-free interest rate	1.1%	2.1%
Expected term (in years)	1.3	1.3
Dividend yield	0.0%	0.0%
Expected volatility	112.0%	99.0%

## 6. Revenue Recognition

We recognize revenue from our collaboration arrangements under ASC Topic No. 808, *Collaboration Arrangements*. Our revenue arrangements with multiple elements are evaluated under ASC Subtopic No. 605-25, *Multiple-Element Arrangements*, and are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of any undelivered items. The consideration we receive is allocated among the separate units based on their respective fair values, and the applicable revenue recognition criteria are applied to each of the separate units. Advance payments received in excess of amounts earned are classified as deferred revenue until earned.

Non-refundable, up-front payments received in connection with research and development collaboration agreements, including technology access fees, are deferred and recognized on a straight-line basis over the relevant periods of continuing involvement, generally the research term. When a research term is not specified, we estimate the time it will take us to complete our deliverables under the contract and recognize the upfront fee using the straight-line method over that time period. We review our estimates every quarter for reasonableness.

Revenues related to collaborative research with our corporate collaborators are recognized as research services are performed over the related development periods for each agreement. Under these agreements, we are required to perform research and development activities as specified in each respective agreement. The payments received are not refundable and are generally based on a contractual cost per full-time equivalent employee working on the project. Our research and development expenses under the collaborative research agreements approximate the revenue recognized under such agreements over the term of the respective agreements. It is our policy to recognize revenue based on our level of effort expended, however, revenue recognized will not exceed amounts billable under the agreement.

Revenues associated with at-risk milestones pursuant to collaborative agreements are recognized upon achievement of the milestones as set forth in the applicable agreement.

7. **Research and Development Accruals**

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

Table of Contents**8. Cash, Cash Equivalents and Available-For-Sale Securities**

Cash, cash equivalents and available-for-sale securities consisted of the following (in thousands):

	September 30, 2009	December 31, 2008
Checking account	\$ 129	\$ 491
Money market funds	80,297	45,514
U. S. treasury bills	26,417	26,085
Government-sponsored enterprise securities	37,140	34,641
Corporate bonds and commercial paper	12,095	27,746
	\$ 156,078	\$ 134,477
Reported as:		
Cash and cash equivalents	\$ 94,745	\$ 46,005
Available-for-sale securities	61,333	88,472
	\$ 156,078	\$ 134,477

Cash equivalents and available-for-sale securities include the following securities with unrealized gains and losses (in thousands):

September 30, 2009	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U. S. treasury bills	\$ 26,408	\$ 9	\$	\$ 26,417
Government-sponsored enterprise securities	37,129	20	(9)	37,140
Corporate bonds and commercial paper	12,097		(2)	12,095
Total	\$ 75,634	\$ 29	\$ (11)	\$ 75,652

December 31, 2008	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U. S. treasury bills	\$ 25,972	\$ 113	\$	\$ 26,085
Government-sponsored enterprise securities	34,501	140		34,641
Corporate bonds and commercial paper	27,603	143		27,746
Total	\$ 88,076	\$ 396	\$	\$ 88,472

As of September 30, 2009, the contractual maturities of our available-for-sale securities were (in thousands):

	Within One Year	Years to Maturity After One Year Through Five Years
U. S. treasury bills	\$ 26,417	\$
Government-sponsored enterprise securities	35,139	2,001
Corporate bonds and commercial paper	12,095	

\$	73,651	\$	2,001
----	--------	----	-------

As of September 30, 2009, our available-for-sale securities had a weighted average time to maturity of approximately 109 days. We view our available-for-sale portfolio as available for use in current operations. Accordingly, we have classified certain available-for-sale investments as short-term in the balance sheet although the stated maturity date may be over one year from the current balance sheet date. We have the ability to hold all investments as of September 30, 2009 to maturity. At September 30, 2009 and December 31, 2008, we had no investments that had been in a continuous unrealized loss position for more than twelve months. As of September 30, 2009, a total of 16 individual securities were in an unrealized loss position for twelve months or less and the losses were deemed to be temporary.

Table of Contents

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

September 30, 2009	Fair Value		Unrealized Losses	
Government-sponsored enterprise securities	\$	21,451	\$	(9)
Corporate bonds and commercial paper		7,095		(2)
Total	\$	28,546	\$	(11)

## 9. Fair Value

Under ASC Topic No. 820, *Fair Value Measurements and Disclosures*, fair value is defined as the price at which an asset could be exchanged or a liability transferred in a transaction between knowledgeable, willing parties in the principal or most advantageous market for the asset or liability. Where available, fair value is based on observable market prices or parameters or derived from such prices or parameters. Where observable prices or parameters are not available, valuation models are applied.

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

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

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

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

The fair valued assets we hold that are generally assessed under Level 2 included government-sponsored enterprise securities, U. S. Treasury bills and corporate bonds and commercial paper where fair value is based on valuation methodologies such as models using observable market inputs, including benchmark yields, reported trades, broker/dealer quotes, bids, offers and other reference data.

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

*Fair Value on a Recurring Basis*

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

	Assets at Fair Value as of September 30, 2009			Total
	Level 1	Level 2	Level 3	
Money market fund	\$ 80,297	\$	\$	\$ 80,297
U. S. treasury bills		26,417		26,417
Government-sponsored enterprise securities		37,140		37,140
Corporate bonds and commercial paper		12,095		12,095
Total	\$ 80,297	\$ 75,652	\$	\$ 155,949



Table of Contents

	Assets at Fair Value as of December 31, 2008			Total
	Level 1	Level 2	Level 3	
Money market fund	\$ 45,514	\$	\$	\$ 45,514
U. S. treasury bills		26,085		26,085
Government-sponsored enterprise securities		34,641		34,641
Corporate bonds and commercial paper		27,746		27,746
Total	\$ 45,514	\$ 88,472	\$	\$ 133,986

***Fair Value on a Non-Recurring Basis***

On March 31, 2009, we issued a new warrant granting our landlord the right to purchase 200,000 shares of common stock, and cancelled an existing warrant to purchase 100,000 shares of common stock, in connection with the amendment of our build-to-suit lease agreement (see Note 11 below for more details). We used the Black Scholes option-pricing model and calculated an incremental fair market value of \$616,000 related to the new warrant in accordance with ASC Topic No. 718. The new warrant was categorized as level 3 under ASC Topic No. 820 due to the unobservable inputs we used in the Black Scholes option-pricing model.

The following table summarizes the assumptions used relating to the valuation of the new warrant:

Risk-free interest rate	2.2%
Expected term (in years)	7.0
Dividend yield	0.0%
Expected volatility	99.2%

**10. Restructuring Charges**

In February 2009, we announced that we cut our research programs in virology and oncology as well as terminated certain related development and administrative staff, which resulted in the dismissal of 36 employees, or approximately 20% of our workforce. As a result of the restructuring, we recorded restructuring charges of \$1.1 million in the first quarter of 2009, including \$1.0 million of workforce reduction costs (which had been substantially paid as of March 31, 2009) and \$122,000 of non-cash stock-based compensation expense as a result of the extension of the date the terminated employees have to exercise their vested options to December 31, 2009 rather than 90 days from the termination date as is typically required under our equity incentive plan.

**11. Amendment to the Build-to-Suit Lease Agreement**

On March 31, 2009, we amended our build-to-suit lease agreement with our landlord, HCP BTC, LLC (formerly known as Slough BTC, LLC), to defer certain rental obligations in the aggregate amount of \$6.9 million for a period of up to seventeen months. Under the terms of this amendment, we are obligated to repay the deferred rental amounts, including interest accruing at 12% during the deferral period, based on a timeline that can vary depending upon the occurrence of certain financing or collaborative transactions. In addition, the amendment to the lease agreement also provided for the cancellation of an existing warrant granting HCP Estates USA Inc. (an affiliate of our landlord) the right to

purchase 100,000 shares of common stock and the issuance of a new warrant granting our landlord the right to purchase 200,000 shares of common stock. The exercise price per share of the new warrant is \$6.61, which is the average closing price of our common stock for the three business days immediately preceding the execution of the amendment to the lease agreement. The new warrant remains exercisable for 7 years from the date of issuance. We applied modification accounting in accordance with ASC Topic No. 718 and calculated an incremental fair market value of the new warrant of \$616,000. This amount has been deferred in other assets and is being amortized into rent expense over the remaining term of the lease.

As discussed in Note 12 below, on September 22, 2009, we completed an underwritten public offering in which we received net proceeds of approximately \$101.5 million after deducting underwriting discounts and commissions and offering expenses. As a result of the above financing, we are obligated to pay our landlord \$3.7 million, or 50% of the deferred rental amounts, plus interest at 12%, within 45 days from the date of closing the public offering. We are obligated to pay the remaining deferred rental amounts, including related interest, of approximately \$4.5 million on or before July 1, 2011.

## **12. Equity Financing**

On September 22, 2009, we completed an underwritten public offering in which we sold 14,950,000 shares of our common stock at a price to the public of \$7.25 per share. We received net proceeds of approximately \$101.5 million after deducting underwriting discounts and commissions and offering expenses.

Table of Contents

**13. Contingencies**

On February 6, 2009, a purported securities class action lawsuit was commenced in the United States District Court for the Northern District of California, naming as defendants us and certain of our officers, directors and underwriters for our February 2008 stock offering. An additional purported securities class action lawsuit containing similar allegations was subsequently filed in the United States District Court for the Northern District of California on February 20, 2009. By order of the Court dated March 19, 2009, the two lawsuits were consolidated into a single action. On April 7, 2009, Inter-Local Pension Fund GCC/IBT filed a motion for appointment as lead plaintiff in the case, and for appointment of its counsel as lead counsel. On June 9, 2009, the Court issued an order naming the Inter-Local Pension Fund GCC/IBT as lead plaintiff and Coughlin Stoia as lead counsel. The lead plaintiff filed an amended complaint on July 24, 2009. The lawsuit alleges violations of the Securities Act of 1933 and the Securities Exchange Act of 1934 in connection with allegedly false and misleading statements made by us related to the results of the Phase 2a clinical trial of our product candidate R788. The plaintiffs seek damages, including rescission or rescissory damages for purchasers in the stock offering, an award of their costs and injunctive and/or equitable relief for purchasers of our common stock during the period between December 13, 2007 and February 9, 2009, including purchasers in the stock offering. We filed a motion to dismiss these claims on September 8, 2009, and a hearing on that motion is set for December 4, 2009. It is possible that additional suits will be filed with respect to these same matters and also naming us and/or our officers and directors as defendants. If any such additional suits are filed in the same court, we believe that they would be consolidated into the consolidated action.

This lawsuit and any other related 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 the litigation is necessarily uncertain and we could be forced to expend significant resources in the defense of this suit, and we may not prevail. We are not currently able to estimate the possible cost to us from this matter, as this lawsuit is currently at an early stage and we cannot ascertain how long it may take to resolve this matter. We have not established any reserve for any potential liability relating to this lawsuit. We believe that we have meritorious defenses and intend to defend this lawsuit vigorously.

Table of Contents

**Report of Independent Registered Public Accounting Firm**

The Board of Directors

Rigel Pharmaceuticals, Inc.

We have reviewed the condensed balance sheet of Rigel Pharmaceuticals, Inc. as of September 30, 2009, and the related condensed statements of operations for the three-month and nine-month periods ended September 30, 2009 and 2008, and the condensed statements of cash flows for the nine-month periods ended September 30, 2009 and 2008. These financial statements are the responsibility of the Company's management.

We conducted our review in accordance with the standards of the Public Company Accounting Oversight Board (United States). A review of interim financial information consists principally of applying analytical procedures and making inquiries of persons responsible for financial and accounting matters. It is substantially less in scope than an audit conducted in accordance with the standards of the Public Company Accounting Oversight Board, the objective of which is the expression of an opinion regarding the financial statements taken as a whole. Accordingly, we do not express such an opinion.

Based on our review, we are not aware of any material modifications that should be made to the condensed financial statements referred to above for them to be in conformity with US generally accepted accounting principles.

We have previously audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheet of Rigel Pharmaceuticals, Inc. as of December 31, 2008, and the related statements of operations, stockholders' equity, and cash flows for the year then ended (not presented herein) and in our report dated February 24, 2009, we expressed an unqualified opinion on those financial statements. In our opinion, the information set forth in the accompanying condensed balance sheet as of December 31, 2008, is fairly stated, in all material respects, in relation to the balance sheet from which it has been derived.

/s/ Ernst & Young LLP

Palo Alto, California  
November 3, 2009

Table of Contents

**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, 2008. Operating results for the three and nine months ended September 30, 2009 are not necessarily indicative of results that may occur in future periods.*

*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, and Section 21E of the Securities Exchange Act of 1934, as amended, that involve risks and uncertainties. We usually use words such as may, will, should, could, expect, plan, anticipate, believe, estimate, predict, intend, or the negative of these terms or similar expressions to identify these forward-looking statements. These statements appear throughout this Quarterly Report on Form 10-Q and are statements regarding our current expectation, belief or intent, primarily with respect to our operations and related industry developments. Examples of these statements include, but are not limited to, statements regarding the following: our business and scientific strategies; the progress of our product development programs, including clinical testing, and the timing of results thereof; our corporate collaborations, including our plan to enter into a collaboration agreement for further development of R788 and revenues that may be received from collaborations; our drug discovery technologies; our research and development expenses; protection of our intellectual property; sufficiency of our cash resources; and our operations and legal risks. You should not place undue reliance on these forward-looking statements. Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including as a result of the risks and uncertainties discussed in the 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. 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 clinical-stage drug development company that discovers and develops novel, small-molecule drugs for the treatment of inflammatory/autoimmune diseases, as well as for certain cancers and metabolic diseases. Our pioneering research focuses on intracellular signaling pathways and related targets that are critical to disease mechanisms. We have product development programs in inflammatory/autoimmune diseases such as rheumatoid arthritis, or RA, thrombocytopenia and asthma, as well as in cancer. R788 is our lead product candidate. We are developing R788 for the treatment of RA, and we recently completed our TASKi2 and TASKi3 Phase 2b clinical trials of R788 in RA patients. We are also developing R788 for the treatment of B-cell and T-cell lymphomas, and in the future intend to develop R788 for the treatment of immune thrombocytopenic purpura, or ITP, and systemic lupus erythematosus based on our previous clinical trials. R788 is also being evaluated by the National Cancer Institute, or NCI, part of the U.S. National Institutes of Health, for the treatment of certain solid tumors. Our other product candidates are being developed for the treatment of psoriasis and possible topical applications, certain cancers and asthma. Our productivity has resulted in strategic collaborations with large pharmaceutical partners to develop and market certain of our product candidates.**

We have not been profitable and have incurred operating losses since we were incorporated in June 1996. The extent of our future losses and the timing of potential profitability are highly uncertain, and we may never achieve profitable operations. We incurred net losses of approximately \$86.5 million for the nine months ended September 30, 2009, \$132.3 million for the year ended December 31, 2008 and \$74.3 million for the year ended December 31, 2007. Currently, our revenues may be generated solely from research milestone payments pursuant to our collaboration agreements and licenses and would be insufficient to generate profitable operations. In addition, we have funded our operations

## Edgar Filing: RIGEL PHARMACEUTICALS INC - Form 10-Q

primarily through private and public offerings of our common stock. As of September 30, 2009, we had an accumulated deficit of approximately \$588.2 million. We expect to incur losses for at least the next several years and expect that these losses could increase as we expand our research and development activities and incur significant clinical and testing costs. Until we are able to generate a sufficient amount of product revenue, we expect to finance future cash needs through collaboration and licensing arrangements or public and/or private equity or debt offerings, as well as through interest income earned on the investment of our cash balances and short-term investments.

For the foreseeable future, our operations will require significant additional funding, in large part due to our research and development expenses, future preclinical and clinical-testing costs, and the absence of any revenues from product sales. The amount of future funds needed will depend largely on the timing and structure of potential future collaborations, including, in particular, with respect to R788. We anticipate that we will enter into a collaboration agreement with respect to R788 in the first half of 2010, but we may not be able to do so on acceptable terms, or at all. With the exception of milestone and royalty payments that we may receive under our existing collaborations, we do not currently have any commitments for future funding. We do not know whether additional financing will be available when needed, or that, if available, we will obtain financing on reasonable terms.

Table of Contents

We continue to pursue a collaboration partner for our lead product candidate, R788, and intend to enter into a collaboration agreement prior to initiating Phase 3 clinical trials. We have engaged in discussions with various parties regarding such a partnership. The recently announced results of our *TASKi2* Phase 2b clinical trial, which showed significant, early and sustained efficacy, combined with a good safety profile supports our plans to conduct corporate partnership discussions with respect to R788 and initiate a Phase 3 clinical trial with R788 in RA in the first half of 2010 with a collaboration partner. We believe the recently announced results of our *TASKi3* Phase 2b clinical trial, which did not meet the primary efficacy endpoint in RA patients who had previously failed biologic therapies, will not prevent us from securing favorable terms with a collaboration partner.

In September 2009, we completed an underwritten public offering in which we sold 14,950,000 shares of our common stock at a price to the public of \$7.25 per share. We received net proceeds of approximately \$101.5 million after deducting underwriting discounts and commissions and offering expenses.

We believe that our existing capital resources will be sufficient to support our current and projected funding requirements 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 the development of our product candidates and other research and development activities, including risks and uncertainties that could impact the rate of progress of our development activities, we are unable to estimate with certainty the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials and other research and development activities.

**Product Development Programs**

Our product development portfolio features multiple novel small molecule drug candidates whose specialized mechanisms of action are intended to provide therapeutic benefit for a range of inflammatory/autoimmune diseases as well as for certain cancers. Our multiple product candidates in development are as follows:

- *R788 (fostamatinib disodium) Product Candidate for Rheumatoid Arthritis (RA).* R788, our lead product candidate, is an orally bio-available inhibitor of spleen tyrosine kinase, or Syk. It has a novel mechanism of action for the treatment of RA, inhibiting receptor signaling of immunoglobulin G, or IgG, in various immune cells, including macrophages and B-cells. RA is an autoimmune disease characterized by chronic inflammation that affects multiple tissues, but typically produces its most pronounced symptoms in the joints. We believe the development of R788 may result in a safe oral disease modifying anti-rheumatic drug that can be used early in the course of the disease, preventing its progression prior to major bone and cartilage destruction.

In July 2009, we announced that R788 produced significant clinical improvement in RA patients in the recently completed *TASKi2* Phase 2b clinical trial in which 457 RA patients were treated for up to six months. *TASKi2* was a multi-center, randomized, double blind, placebo controlled, parallel dose clinical trial involving RA patients in the U.S., Latin America and Europe who had failed to respond to methotrexate alone. Patients received either 100 mg of R788 bid (twice a day), 150 mg qd (once a day) or placebo bid or qd. Efficacy assessments for each participant were based on the American College of Rheumatology criteria, which denotes at least a 20% (ACR 20) improvement, at least a 50% (ACR 50) improvement, or at least a 70% (ACR 70) improvement, as well as improvement in the Disease Activity Score (DAS28), from the baseline assessment at the end of the six month treatment period. The groups treated with 100 mg of R788 bid and 150 mg qd reported higher ACR 20, ACR 50, ACR 70 and DAS28 response rates than the placebo group. The efficacy results for the two dosing groups were comparable, although the response rates for the 100 mg bid group was uniformly greater. Consistent with the previous Phase 2a clinical trial (*TASKi1*), the

onset of effect of R788 occurred within one week after the initiation of therapy and was maintained. The most frequent adverse events were expected based on *TASKi1* and appear to be manageable. The most common clinically meaningful drug-related adverse events noted in *TASKi2* were diarrhea and hypertension. Dose reduction options were pre-specified in the trial protocol and, in cases where doses were reduced, patients generally completed the clinical trial with minimal safety issues. The mean increase in blood pressure from baseline at six months, using a last observation carry forward methodology, was less than 0.5 mmHg for the 150 mg qd dose group and approximately 1 mmHg for the 100mg bid dose group. In patients that had a history of high blood pressure, an elevated blood pressure level at screening or baseline, or were on blood pressure medication, approximately 29% and 39% of these patients in the 150 mg qd dose and the 100 mg bid dose groups, respectively, had blood pressure medication adjusted or initiated during the course of the study, compared with 12% of these patients from the placebo group. In patients that did not have a history of high blood pressure, were not on blood pressure medication or did not have an elevated blood pressure level at screening or baseline, approximately 4% and 9% of these patients from the 150 mg qd dose and the 100 mg bid dose groups, respectively, had blood pressure medication initiated during the course of the study, compared with 3% of these patients from the placebo group. For those patients who had their dose of blood pressure medications adjusted or initiated, their blood



Table of Contents

pressure was successfully reduced and was generally well controlled throughout the remainder of the trial. The blood pressure medications were standard doses of common blood pressure medication such as angiotensin-converting enzyme, or ACE, inhibitors or diuretics. The most common adverse events in the trial overall were related to infections, though these were generally evenly distributed among the placebo and R788 groups.

In July 2009, we also announced results for the *TASKi3* Phase 2b clinical trial involving 219 RA patients who had failed to respond to at least one biologic treatment. In the *TASKi3* clinical trial, patients received either 100 mg of R788 bid or placebo bid for up to three months. The group treated with R788 did not report significantly higher ACR 20, ACR 50, ACR 70 and DAS28 response rates than the placebo group at three months, and therefore, the trial failed to meet its efficacy endpoints. The objective components (C-Reactive Protein and Erythrocyte Sedimentation Rate) of these ACR scores did show a statistically significant difference; however, the subjective reported response rate components did not as compared to placebo. Although the ACR scores for the R788 group were within the expected range in this patient population, the reported placebo response rates were considerably higher than seen in any other previous study of RA biologic failure patients and rose unaccountably between week six (at which point the reported response rates between R788 and placebo were significantly different) and month three (when such reported response rates were no longer significantly different). *TASKi3* was the first clinical trial for R788 in which anatomical changes in the patients' wrists and hands were evaluated using Magnetic Resonance Imaging and scored using the RAMRIS (Rheumatoid Arthritis Magnetic Resonance Imaging Scoring) system. Those results showed improvements in the treated group versus the placebo group in the Synovitis and Osteitis scores, while the Erosion scores, known to be the slowest to change, showed no significant effect at three months. Similar to *TASKi2*, the most common clinically meaningful drug-related adverse events noted in *TASKi3* were diarrhea and hypertension. Dose reduction options were pre-specified in the trial protocol and, in cases where doses were reduced, patients generally completed the clinical trial with minimal safety issues. The mean increase in blood pressure from baseline at three months, using a last observation carry forward methodology, was 3.2 - 3.6 mmHg for the R788 group. In *TASKi3*, patients that had a history of high blood pressure, had an elevated blood pressure level at screening or baseline, or were on blood pressure medication, approximately 26% of these patients had blood pressure medication adjusted or initiated during the course of the study, compared with 14% of these patients from the placebo group. In patients that did not have a history of high blood pressure, were not on blood pressure medication or did not have an elevated blood pressure level at screening or baseline, approximately 5% of these patients had blood pressure medication initiated during the course of the study, compared with 3% of these patients from the placebo group. For those patients who had their dose of blood pressure medications adjusted or initiated, their blood pressure was successfully reduced and was generally well controlled throughout the remainder of the trial. The blood pressure medications were standard doses of common blood pressure medications such as ACE inhibitors or diuretics. The most common adverse events in the trial overall were related to infections, though these were generally evenly distributed among the placebo and R788 groups.

In February 2009, we announced favorable results in a QTc study for R788, which was conducted to evaluate the cardiac safety of R788. The double-blind, double-dummy, randomized, positive and placebo controlled parallel study of the effects of R788 on QT/QTc intervals in healthy subjects showed that R788 does not elicit a QT/QTc signal. Under a protocol pre-reviewed by the U.S. Food and Drug Administration, or the FDA, a total of 208 healthy volunteers were divided into four dosage groups and were given, in a parallel design, either placebo, a standard dose of 100 mg bid of R788, a super dose of 300 mg bid of R788, or moxifloxacin (known to elevate QT/QTc intervals in normal healthy adults). All participants were dosed for four days and were evaluated for changes from the time-matched baseline QT/QTc intervals using extractions from continuous Holter monitors. There were no significant effects on the QT/QTc intervals of participants in either the 100 mg bid or the 300 mg bid R788 dosage groups. As expected, the study found that participants in the moxifloxacin group experienced QT/QTc elevations.

In October 2009, we met with representatives of the U.S. FDA to discuss the clinical profile of R788 and our proposed Phase 3 development plan for patients with RA. As a result of that meeting, we expect to move forward with the plan we proposed to the FDA, including the initiation of a Phase 3 clinical trial in the first half of 2010 with a partner, pending the completion of collaboration arrangement. We plan to interact with representatives of the European Medicines Agency, or EMEA, by the end of 2009 to discuss the European approval requirements. We continue to pursue a collaboration partner for R788 with the intent to enter into a collaboration agreement prior to initiating a Phase 3 clinical trial evaluating R788 in RA patients. We have engaged in discussions with various parties regarding such a collaboration and, if we are able to enter into a collaboration for R788 in a timely manner, we plan to initiate a Phase 3 clinical trial evaluating R788 in RA in the first half of 2010 with the collaboration partner.

- *R788 Product Candidate for B-Cell Lymphoma.* Lymphoma is a large class of blood cancers that affect the lymphatic system, which is part of the immune system. Research has shown that over activity of the signaling enzyme Syk appears to have an essential role in the survival and proliferation of certain B-cell lymphoma cell lines, and that R788 can inhibit the growth of B-cell lymphoma driven by Syk over activity.

Table of Contents

In December 2008, we reported the results of a Phase 2 clinical trial that showed R788 was well-tolerated by B-cell lymphoma patients and that also showed therapeutic benefit in patients suffering from diffuse large B-Cell lymphoma, or DLBCL, and chronic lymphocytic leukemia/small lymphocytic lymphoma, or CLL/SLL. A total of 68 patients received 200 mg PO bid (orally, twice daily) of R788 until disease progression occurred. Treatment response rates from patients suffering from DLBCL and CLL/SLL were 22% and 55%, respectively. Response to treatment was evaluated using standard non-Hodgkin's lymphoma response criteria (The Cheson Criteria). Treatment-related adverse events included cytopenias, fatigue, diarrhea/abdominal discomfort and hypertension. Most adverse events were mild to moderate and were reversible.

- *R788 Product Candidate for T-Cell Lymphoma.* Recent research has suggested that Syk may be important in the growth of some types of T-cell lymphomas.

In March 2009, we announced the enrollment of the first patient in a Phase 2, multi-center clinical trial of R788 in patients with refractory or relapsed peripheral T-cell lymphoma, or PTCL. The primary objective of the clinical trial is to assess the efficacy of R788 in patients suffering from this subset of non-Hodgkin's lymphoma that originates in the patient's T-cells. Prior studies have suggested increased expression of Syk at the cellular level in many of these patients with PTCL.

The Phase 2 clinical trial is being conducted in two stages at several centers in North America, with each patient receiving 200mg of R788 orally twice a day for a minimum of eight weeks, or until disease progression or withdrawal from the clinical trial. During stage one, 19 patients with PTCL who previously failed to respond to standard of care treatment for their disease are expected to be evaluated. Stage two is expected to include the enrollment of approximately 36 patients. Efficacy will be assessed by computerized tomography/positron emission tomography scans at baseline and CT scans of the disease-involved areas at eight weeks. Safety will be assessed by periodic physical exams, blood tests and clinical laboratory work, among others. Results of the clinical trial are expected in the second half of 2010.

- *R788 Product Candidate for Certain Solid Tumors.* Recent research has suggested that Syk may be important in the growth of certain solid tumors.

In June 2009, we announced that R788 is being evaluated in a Phase 2 clinical trial funded, designed and implemented by the NCI. This open-label, single arm clinical trial includes patients with advanced colorectal, thyroid, non-small cell lung, hepatocellular, head and neck, or renal cell cancers who failed to respond to at least one line of therapy. The NCI is conducting the clinical trial and we supply the study drug and will receive clinical data and trial results.

- *R788 Product Candidate for Immune Thrombocytopenic Purpura (ITP).* Platelet destruction from ITP is mediated by IgG signaling, which signaling pathway is potently inhibited by R788. In pre-clinical studies, R788 was shown to improve thrombocytopenia in a mouse model of ITP. We completed an exploratory Phase 2 clinical trial of R788 to evaluate its safety and initial efficacy in chronic ITP patients. In this clinical trial, R788 was orally administered in varying doses for 30 or more days and demonstrated that it can improve platelet counts in highly refractory patients. We have postponed expanding this clinical trial of R788 in ITP until we secure a collaboration partner for R788 and have further clarity on the development priorities of such partner.

## Edgar Filing: RIGEL PHARMACEUTICALS INC - Form 10-Q

- *R788 Product Candidate for Systemic Lupus Erythematosus (SLE or Lupus).* SLE is an autoimmune disease characterized by excessive and chronic activation of inflammatory pathways. The disease leads to inflammation-mediated organ damage (kidney, brain, joints, and blood vessels). Pre-clinical studies have shown that R788 is highly effective in a mouse model of lupus. The initiation of a clinical trial in lupus patients has been postponed until we secure a collaboration partner for R788 and have further clarity on the development priorities of such partner.

- *R348 Product Candidate for Psoriasis and Other Immune Disorders.* R348 is a potent and selective janus tyrosine kinase 3, or JAK3, inhibitor. JAK3 is a cytoplasmic tyrosine kinase that plays an important role in modulating cytokine signaling in T and B cells, as well as affecting lymphocyte differentiation and proliferation in a variety of autoimmune diseases.

We completed a Phase 1 clinical trial of R348, indicating a favorable safety profile. Moving forward, we plan to focus on psoriasis and possible topical applications of R348 in conjunction with a potential collaboration partner.

We are currently in the process of selecting a lead candidate for our oral JAK3 inhibitor program for the treatment of transplant rejection, and we expect to identify this lead candidate in 2009.

- *R763 Product Candidate for Oncology.* R763/AS703569 is a potent, highly-selective, small-molecule inhibitor of aurora kinase. Aurora kinase plays a central role in cell division, and its over-expression has been associated with several cancer types. Inhibition of aurora kinase is thus believed to be a potential treatment for many different types of cancer.

Table of Contents

In October 2005, we signed a licensing agreement with Merck Serono S.A., or Merck Serono, that gave Merck Serono an exclusive license to develop and commercialize inhibitors in our aurora kinase program, including R763/AS703569. In November 2007, Merck Serono exercised its option to add Japan to the territories covered under the current aurora kinase collaboration with respect to R763/AS703569, resulting in a milestone payment to us of \$3.0 million. Under the agreement, Merck Serono is responsible for the further development and commercialization of R763/AS703569. In September 2006, Merck Serono initiated a Phase 1, multi-center clinical trial to evaluate R763/AS703569 for the treatment of patients with refractory solid tumors. In February 2007, Merck Serono began an additional Phase 1 clinical trial evaluating R763/AS703569 on patients with hematological malignancies. In July 2007, Merck Serono initiated its third Phase 1 clinical trial, designed to determine the maximum tolerated dose, safety and dosing regimen of R763/AS703569 in combination with gemcitabine, a commonly prescribed chemotherapeutic agent administered by intravenous infusion. The clinical trial is evaluating two different treatment regimens in which R763/AS703569 is being given in sequence with the gemcitabine over 21-day cycles. As many as 72 patients with advanced malignancies, including pancreatic, ovarian, breast, non-small cell lung and colorectal cancers, are being evaluated. We expect that Merck Serono will initiate two Phase 2 clinical trials by the first half of 2010.

- *R343 Product Candidate for Asthma.* R343 is a potent Syk inhibitor that blocks immunoglobulin E, or IgE, receptor signaling. Allergic asthma is a potentially life-threatening chronic inflammatory disorder of the airways which, in some patients, is mediated by allergen-induced IgE antibodies that trigger intracellular signaling in mast cells via IgE receptors. Mast cells play important roles in both early and late phase allergic reactions, and Syk inhibitors could potentially prevent both phases.

In the first quarter of 2005, we announced a collaborative research and license agreement with Pfizer, Inc., or Pfizer, for the development of inhaled products for the treatment of allergic asthma and other respiratory diseases, such as chronic obstructive pulmonary disease. The collaboration was focused on our pre-clinical small molecule compounds which inhibit Syk. The collaboration is now centered on the development of R343. Pfizer has completed the Phase 1a clinical trial of an inhaled formulation of R343, which commenced in December 2007, resulting in a milestone payment of \$5.0 million to us. Pfizer initiated a Phase 1b allergen challenge clinical trial in the second quarter of 2009. We expect that Pfizer will initiate a Phase 2 clinical trial in 2010.

**Corporate Collaborations**

We conduct research and development programs independently and in connection with our corporate collaborators. We currently have collaborations with six major pharmaceutical/biotechnology companies. These collaborations are:

- Janssen Pharmaceutica N.V., a division of Johnson & Johnson, relating to oncology therapeutics and diagnostics;
- Pfizer, Inc., one initiated in 1999 in immunology and the other in January 2005, relating to intrapulmonary asthma and allergy therapeutics;
- Novartis Pharma AG, or Novartis, with respect to four different programs relating to immunology, oncology and chronic bronchitis;

- Daiichi Pharmaceuticals Co., Ltd., or Daiichi, relating to oncology;
- Merck & Co., Inc., or Merck, also relating to oncology; and
- Merck Serono, relating to our aurora kinase inhibitor program.

None of these collaborations currently provides us with regular research reimbursement, and we have not derived any revenues from any of these collaborations since 2007. In all of these collaborations, if certain conditions are met, we are entitled to receive future milestone payments and royalties. We cannot guarantee that these conditions will be met or that research and development efforts will be successful. As a result, we may not receive any further milestone payments or royalties under these agreements.

#### **Research and Development Expenses**

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

Table of Contents

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

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

The following table presents our total research and development expenses by category.

Categories:	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Research	\$ 4,348	\$ 6,479	\$ 13,536	\$ 18,460
Development	10,088	17,398	38,084	40,633
Other	6,646	7,355	18,948	22,175
	\$ 21,082	\$ 31,232	\$ 70,568	\$ 81,268

We have not tracked research and development expenses to date in these categories prior to our preparation of this Quarterly Report on Form 10-Q. Other expenses above mainly represent allocated stock-based compensation expenses of approximately \$2.4 million and \$3.0 million for the three months ended September 30, 2009 and 2008, respectively, and allocated facilities costs of approximately \$4.3 million for the three months ended September 30, 2009 and 2008. For the nine months ended September 30, 2009 and 2008, allocated stock-based compensation expenses were approximately \$6.3 million and \$9.2 million, respectively, and allocated facilities costs were approximately \$12.7 million and \$13.0 million, respectively.

For the three and nine months ended September 30, 2009 and 2008, respectively, the major portion of our research and development expenses were associated with our two Phase 2b clinical trials (*TASKi2* and *TASKi3*), as well as the related extension trials in RA patients. The expenses for these programs are included in Development expenses above.

The scope and magnitude of future research and development expenses are difficult to predict given the number of clinical trials that we will need to conduct for any of our potential products, as well as our limited capital resources. Preclinical testing and clinical development are long, expensive and uncertain processes. In general, biopharmaceutical development involves a series of steps, beginning with identification of a potential target and including, among others, proof of concept in animals and Phase 1, 2 and 3 clinical trials in humans. Each of these steps is typically more expensive than the previous step. Success in early stages of development often results in increasing expenditures for a given

product candidate. 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 trial at a prospective clinical site or delays in recruiting subjects to participate in a study.

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



Table of Contents

and efficacy, which could prevent or significantly delay regulatory approval. We do not have a reasonable basis to determine when or if material net cash inflows from the commercialization and sale of our drug candidates will occur. Commercialization of our product candidates depends upon successful completion of extensive preclinical studies and clinical trials to demonstrate their safety and efficacy for humans. We do not know whether we, or any of our current or potential future collaborative partners, will undertake clinical trials of potential products beyond the trials already concluded and the trials currently in process. It will take us, or our current or potential future 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. Moreover, we or our current or potential future collaborative partners may decide to discontinue development of any project at any time for regulatory, commercial, scientific or other reasons. To date, we have not commercialized any of our drug candidates, and we may never do so.

For a discussion of the risks and uncertainties associated with the timing and costs of completing the development of the Company's drug candidates, see Part II. Item 1A. Risk Factors, including in particular the following risks:

- Our future funding requirements will depend on many uncertain factors.
- We might not be able to commercialize our product candidates successfully if problems arise in the clinical testing and approval process.
- There is a high risk that drug discovery and development efforts might not successfully generate good product candidates.
- Delays in clinical testing could result in increased costs to us.
- Because we expect to be dependent upon collaborative and license agreements, we might not meet our strategic objectives.
- If our corporate collaborations or license agreements are unsuccessful, our research and development efforts could be delayed.
- 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.

For further discussion on research and development activities, see Research and Development Expenses under Results of Operations below.

**Equity Financing**

In September 2009, we completed an underwritten public offering in which we sold 14,950,000 shares of our common stock at a price to the public of \$7.25 per share. We received net proceeds of approximately \$101.5 million after deducting underwriting discounts and commissions and offering expenses.

**Recent Accounting Pronouncements**

In October 2009, the FASB issued Accounting Standards Update, or ASU, No. 2009-13 (formerly Emerging Issues Task Force, or EITF, No. 08-1) on ASC Topic No. 605 for revenue recognition related to multiple-deliverable revenue arrangements. The ASU provides amendments to the existing criteria for separating consideration in multiple-deliverable arrangements. The amendments establish a selling price hierarchy for determining the selling price of a deliverable, eliminate the residual method of allocation of arrangement consideration to all deliverables and require the use of the relative selling price method in allocation of arrangement consideration to all deliverables, require the determination of the best estimate of a selling price in a consistent manner, and significantly expand the disclosures related to the multiple-deliverable revenue arrangements. The amendments will be effective in fiscal years beginning on or after June 15, 2010, and early adoption is permitted. We are currently evaluating the impact on our financial statements of adopting these amendments to ASC Topic No. 605 and cannot estimate the impact of adoption at this time.

On July 1, 2009, the FASB launched the FASB Accounting Standards Codification<sup>TM</sup>, or the Codification, as the single source of authoritative U.S. GAAP recognized by the FASB. The Codification reorganizes various U.S. GAAP pronouncements into accounting topics and displays them using a consistent structure. All existing accounting standards documents are superseded as described in SFAS No. 168, *The FASB Accounting Standards Codification<sup>TM</sup> and the Hierarchy of Generally Accepted Accounting Principles* which is now part of ASC Topic No. 105. All of the contents of the Codification carry the same level of authority, effectively superseding SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*, which identified and ranked the sources of accounting principles and the framework for selecting the principles used in preparing the financial statements in conformity with U.S. GAAP. Also included in the Codification, as a reference for public companies, are rules and interpretive releases of the U.S. Securities and Exchange Commission, or the SEC, under authority of federal securities laws which are also sources of authoritative U.S. GAAP for SEC registrants. The Codification is effective for interim and annual periods ending after September 15, 2009. We adopted SFAS No. 168 on July 1, 2009 and concluded it had no material impact on our financial statements other than changing the way specific accounting standards are referenced in our financial statements.

Table of Contents

**Critical Accounting Policies and the Use of Estimates**

Our discussion and analysis of our financial condition and results of operations is based upon our financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. We evaluate our estimates, including those related to terms of our research collaborations (i.e. revenue recognition of upfront fees and certain milestone payments), investments, stock-based compensation, impairment issues, the estimated useful life of assets and contingencies, on an on-going basis. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our financial statements:

***Revenue Recognition***

We recognize revenue from our collaboration arrangements under ASC Topic No. 808, *Collaboration Arrangements*. Our revenue arrangements with multiple elements are evaluated under ASC Subtopic No. 605-25, *Multiple-Element Arrangements*, and are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of any undelivered items. The consideration we receive is allocated among the separate units based on their respective fair values, and the applicable revenue recognition criteria are applied to each of the separate units. Advance payments received in excess of amounts earned are classified as deferred revenue until earned.

Non-refundable, up-front payments received in connection with research and development collaboration agreements, including technology access fees, are deferred and recognized on a straight-line basis over the relevant periods of continuing involvement, generally the research term. When a research term is not specified, we estimate the time it will take us to complete our deliverables under the contract and recognize the upfront fee using the straight-line method over that time period. We review our estimates every quarter for reasonableness.

Revenues related to collaborative research with our corporate collaborators are recognized as research services are performed over the related development periods for each agreement. Under these agreements, we are required to perform research and development activities as specified in each respective agreement. The payments received are not refundable and are generally based on a contractual cost per full-time equivalent employee working on the project. Our research and development expenses under the collaborative research agreements approximate the revenue recognized under such agreements over the term of the respective agreements. It is our policy to recognize revenue based on our level of effort expended, however, revenue recognized will not exceed amounts billable under the agreement.

Revenues associated with at-risk milestones pursuant to collaborative agreements are recognized upon achievement of the milestones as set forth in the applicable agreement.

***Stock-based Compensation***

## Edgar Filing: RIGEL PHARMACEUTICALS INC - Form 10-Q

The determination of the fair value of stock-based payment awards on the date of grant using the Black-Scholes option-pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, volatility, expected term, risk-free interest rate and dividends. We estimate volatility using our historical stock price performance over the expected life of the option up to the point where we have historical market data. For expected term, among other things, we take into consideration our historical data of options exercised, cancelled and expired. The risk-free rate is based on the U.S. Treasury constant maturity rate. We have not paid and do not expect to pay dividends in the foreseeable future. In order to calculate stock-based compensation expense, we also estimate the forfeiture rate using our historical experience with options that cancel before they vest.

### *Research and Development Accruals*

We have various contracts with third parties related to our research and development activities. Costs that are incurred but not billed to us as of the end of the period are accrued. We make estimates of the amounts incurred in each period based on the information available to us and our knowledge of the nature of the contractual activities generating such costs. Clinical trial contract expenses are accrued based on units of activity reported by third parties. Expenses related to other research and development

Table of Contents

contracts, such as research contracts, toxicology study contracts and manufacturing contracts are estimated to be incurred generally on a straight-line basis over the duration of the contracts. Raw materials and study materials purchased by third parties are expensed at the time of purchase. Many of our estimates are based significantly or in part on information provided by third parties. If such information were not reported properly, our research and development expense amounts could be misstated.

**Results of Operations****Three and Nine Months Ended September 30, 2009 and 2008****Revenues**

There were no revenues reported during the three and nine months ended September 30, 2009 and 2008. We had no deferred revenue as of September 30, 2009. Our potential future revenues may include certain milestone payments and royalties from our current collaboration partners or potential revenue from new collaboration partners with whom we enter into agreements in the future.

**Research and Development Expenses**

	Three Months Ended September 30, 2009		Aggregate Change	Nine Months Ended September 30, 2009		Aggregate Change
	(in thousands)			(in thousands)		
	2009	2008		2009	2008	
<b>Research and development expenses</b>	\$ 21,082	\$ 31,232	\$ (10,150)	\$ 70,568	\$ 81,268	\$ (10,700)
<b>Stock-based compensation expense included in research and development expenses</b>	2,356	3,035	(679)	6,309	9,229	(2,920)

The decrease in research and development expenses for the three months ended September 30, 2009, compared to the same period in 2008, was primarily due to the completion of our two Phase 2b clinical trials (*TASKi2* and *TASKi3*), and cost savings as a result of the restructuring implemented in the first quarter of 2009, as discussed under **Restructuring Charges** below, combined with a decrease in stock-based compensation expense as discussed under **Stock-Based Compensation** below.

The decrease in research and development expenses for the nine months ended September 30, 2009, compared to the same period in 2008, was primarily due to a decrease in stock-based compensation expense as discussed under **Stock-Based Compensation** below, a decrease in clinical trial costs associated with the completion of our two Phase 2b clinical trials (*TASKi2* and *TASKi3*), and cost savings as a result of the restructuring implemented in the first quarter of 2009, as discussed under **Restructuring Charges** below.

## General and Administrative Expenses

	Three Months Ended September 30, 2009		September 30, 2008 (in thousands)		Aggregate Change	Nine Months Ended September 30, 2009		September 30, 2008 (in thousands)		Aggregate Change		
<i>General and administrative expenses</i>	\$	5,573	\$	7,450	\$	(1,877)	\$	15,226	\$	21,436	\$	(6,210)
<i>Stock-based compensation expense included in general and administrative expenses</i>		1,176		3,001		(1,825)		3,226		8,572		(5,346)

The decreases in general and administrative expenses for the three and nine months ended September 30, 2009, as compared to the same periods in 2008, were primarily attributable to a decrease in stock-based compensation expense as discussed under [Stock-Based Compensation](#) below, and decreased patent expenses due to active efforts to reduce patent-based costs and decreased international filing needs.

Table of Contents**Restructuring Charges**

	Three Months Ended September 30, 2009		Aggregate Change	Nine Months Ended September 30, 2009		Aggregate Change	
	(in thousands)			(in thousands)			
<b>Restructuring Charges</b>	\$	\$	\$	\$	1,141	\$	1,141
<b>Stock-based compensation expense included in restructuring charges</b>					122		122

In February 2009, we announced that we cut our research programs in virology and oncology as well as terminated certain related development and administrative staff, which resulted in the dismissal of 36 employees, or approximately 20% of our workforce. This measure was intended to maintain our emphasis on our active preclinical and clinical programs, while conserving our resources. As a result of the restructuring implemented in the first quarter of 2009, we recorded restructuring charges of \$1.1 million, including \$1.0 million of workforce reduction costs (which had been substantially paid as of March 31, 2009) and \$122,000 of non-cash stock-based compensation expense as a result of the extension of the date the terminated employees have to exercise their vested options to December 31, 2009 rather than 90 days from the termination date as is typically required under our equity incentive plan.

**Stock-Based Compensation**

	Three Months Ended September 30, 2009		Aggregate Change	Nine Months Ended September 30, 2009		Aggregate Change						
	(in thousands)			(in thousands)								
<b>Stock-based compensation expense from:</b>												
<b>Officer, director and employee options</b>	\$	3,501	\$	6,027	\$	(2,526)	\$	9,590	\$	17,607	\$	(8,017)
<b>Consultant options</b>		31		9		22		67		194		(127)
<b>Total</b>	\$	3,532	\$	6,036	\$	(2,504)	\$	9,657	\$	17,801	\$	(8,144)

The decreases in stock-based compensation expense for the three and nine months ended September 30, 2009, as compared to the same periods in 2008, were primarily due to the lower valuation of options granted in the first quarter of 2009 and the full recognition of most of the expense associated with the options granted in the first quarter of 2008 as of the end of 2008, as most of these options vest over a one year period.

**Interest Income**

	Three Months Ended September 30, 2009		Aggregate Change	Nine Months Ended September 30, 2009		Aggregate Change						
	(in thousands)			(in thousands)								
<b>Interest income</b>	\$	48	\$	1,034	\$	(986)	\$	554	\$	3,853	\$	(3,299)

## Edgar Filing: RIGEL PHARMACEUTICALS INC - Form 10-Q

Interest income results from our interest-bearing cash and investment balances. The decreases in interest income for the three and nine months ended September 30, 2009, as compared to the same periods in 2008, were due to a lower cash balance that earned interest and lower interest rates earned on our investments in the 2009 periods. The net proceeds of our underwritten public offering of approximately \$101.5 million were received at the end of September 2009 and therefore did not impact interest income during the period.

### Interest Expense

	Three Months Ended September 30,		Aggregate Change	Nine Months Ended September 30,		Aggregate Change
	2009	2008 (in thousands)		2009	2008 (in thousands)	
<i>Interest expense</i>	\$ 44	\$ 43	\$ 1	\$ 166	\$ 131	\$ 35



Table of Contents

Interest expense results from our capital lease obligations associated with fixed asset acquisitions. Interest expense was relatively flat for the three months ended September 30, 2009 and 2008. The increase in interest expense for the nine months ended September 30, 2009, as compared to the same period in 2008, was due to the higher outstanding balances on capital lease obligations during the first half of 2009.

**Income tax benefit**

	Three Months Ended September 30,		Aggregate Change	Nine Months Ended September 30,		Aggregate Change
	2009	2008 (in thousands)		2009	2008 (in thousands)	
<i>Income tax benefit</i>	\$	\$	\$	\$	93	\$ 93

We recorded an income tax benefit of approximately \$93,000 for the nine months ended September 30, 2009 to reflect tax refunds in accordance with the provisions of the American Recovery and Reinvestment Act of 2009.

**Liquidity and Capital Resources****Cash Requirements**

We have financed our operations from inception primarily through sales of equity securities, contract payments under our collaboration agreements and equipment financing arrangements. We have consumed substantial amounts of capital to date, and our operating expenditures are expected to increase over the next several years, in large part due to our research and development expenses, future preclinical and clinical testing costs and the absence of any revenues from product sales.

As of September 30, 2009, we had approximately \$156.1 million in cash, cash equivalents and available-for-sale securities, as compared to approximately \$134.5 million as of December 31, 2008, an increase of approximately \$21.6 million. The increase was primarily attributable to net proceeds of approximately \$101.5 million from our public offering in the third quarter of 2009, offset by operating expenses for the nine months ended September 30, 2009. We believe that our existing capital resources will be sufficient to support our current and projected funding requirements through at least the next twelve 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 the development of our product candidates and other research and development activities, including risks and uncertainties that could impact the rate of progress of our development activities, we are unable to estimate with certainty the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials and other research and development activities.

Our operations will require significant additional funding for the foreseeable future. The amount of future funds needed will depend largely on the timing and structure of potential future collaborations, including in particular with respect to R788. We anticipate that we will enter into a collaboration agreement with respect to R788 in the first half of 2010, but we may not be able to do so on acceptable terms, or at all. Until we are able to generate a sufficient amount of product revenue, we expect to finance future cash needs through public and/or private equity

offerings, debt financings or collaboration and licensing arrangements, as well as through interest income earned on the investment of our cash balances and short-term investments. With the exception of milestone and royalty payments that we may receive under our existing collaborations, we do not currently have any commitments for future funding. Recently, the credit markets and the financial services industry have been experiencing a period of unprecedented turmoil and upheaval characterized by the bankruptcy, failure, collapse or sale of various financial institutions and an unprecedented level of intervention from the United States federal government. These events have generally made equity and debt financing more difficult to obtain. As a result of these and other factors, we do not know whether additional financing will be available when needed, or that, if available, we will obtain financing on reasonable terms.

To the extent we raise additional capital by issuing equity securities, our stockholders could at that time experience substantial dilution. Any debt financing that we are able to obtain may involve operating covenants that 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:

- our ability to establish new collaborations and the terms thereof;

Table of Contents

- the progress and success of clinical trials and preclinical activities (including studies and manufacture of materials) of our product candidates conducted by us or our collaborative partners or licensees;
- the progress of research programs carried out by us;
- any changes in the breadth of our research and development programs;
- our ability to meet the milestones identified in our collaborative agreements that trigger payments to us from our collaboration partners;
- the progress of the research and development efforts of our collaborative partners;
- our ability to acquire or license other technologies or compounds that we 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 intellectual property rights;
- the costs and timing of regulatory approvals and filings by us and our collaborators; and
- expenses associated with the pending and potential additional related purported securities class action lawsuits, as well as any unforeseen litigation.

Insufficient funds may require us to delay, scale back or eliminate some or all of our 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

## Edgar Filing: RIGEL PHARMACEUTICALS INC - Form 10-Q

would otherwise choose or may adversely affect our ability to operate as a going concern. For the nine months ended September 30, 2009 and 2008, we maintained an investment portfolio primarily in money market funds, U.S. treasury bills, government-sponsored enterprise securities, and corporate bonds and commercial paper. Cash in excess of immediate requirements is invested with regard to liquidity and capital preservation. Wherever possible, we seek to minimize the potential effects of concentration and degrees of risk.

### Cash Flows from Operating, Investing and Financing Activities

	Nine Months Ended September 30,	
	2009	2008
Net cash used in operating activities	\$ (79,505)	\$ (76,378)
Net cash provided by (used in) investing activities	26,666	(40,816)
Net cash provided by financing activities	101,579	130,409
Net increase in cash and cash equivalents	\$ 48,740	\$ 13,215

Net cash used in operating activities was \$79.5 million for the nine months ended September 30, 2009, compared to \$76.4 million for the nine months ended September 30, 2008. The increase in net cash used in operating activities was primarily due to the increase in cash payments related to our research and development programs. The timing of cash requirements may vary from period to period depending on our research and development activities, including our planned preclinical and clinical trials, and future requirements to establish commercial capabilities for any products that we may develop.

Net cash provided by investing activities was \$26.7 million for the nine months ended September 30, 2009, compared to net cash used in investing activities of \$40.8 million for the nine months ended September 30, 2008. Net cash provided by investing activities in 2009 was primarily due to maturities of available-for-sale securities of \$101.4 million and sale of available-for-sale securities of \$8.2 million, partially offset by purchases of available-for-sale securities of \$82.9 million. Net cash used in investing activities for the nine months ended September 30, 2008 related primarily to purchases of short-term investments of \$170.1 million, partially offset by maturities of short-term investments of \$131.1 million. Capital expenditures were approximately \$95,000 for the nine months ended September 30, 2009, compared to \$1.8 million for the same period in 2008.

Table of Contents

Net cash provided by financing activities was approximately \$101.6 million for the nine months ended September 30, 2009, compared to approximately \$130.4 million for the same period in 2008. In the third quarter of 2009, we completed a public offering in which we received net proceeds of approximately \$101.5 million after deducting underwriting discounts and commissions and offering expenses. Net cash provided by financing activities for the nine months ended September 30, 2009 also included proceeds from the exercise of outstanding options and the issuance of shares under our ESPP of approximately \$1.2 million, partially offset by payments of capital lease obligations of approximately \$1.1 million. In the first quarter of 2008, we completed a public offering in which we received net proceeds of approximately \$127.5 million after deducting underwriting discounts and commissions and offering expenses. We also received proceeds from the exercise of outstanding options and the issuance of shares under our ESPP of approximately \$2.4 million during the nine months ended September 30, 2008. Proceeds from capital lease financing were approximately \$1.4 million and payments for capital lease financing were approximately \$903,000 during the nine months ended September 30, 2008.

**Off-Balance Sheet Arrangements**

As of September 30, 2009, we had no off-balance sheet arrangements (as defined in Item 303(a)(4)(ii) of Regulation S-K under the Securities Exchange Act of 1934, as amended) that create potential material risks for us and that are not recognized on our balance sheets.

**Contractual Obligations**

As of September 30, 2009, we had the following contractual commitments:

	Total	Less than 1 Year	Payment Due By Period		
			1 - 3 Years	3 - 5 Years	More than 5 years
			(in thousands)		
<b>Capital Lease obligations (1)</b>	<b>\$ 2,409</b>	<b>\$ 1,213</b>	<b>\$ 1,196</b>	<b>\$ 27,890</b>	<b>\$ 51,562</b>
<b>Facilities lease (2)</b>	<b>126,520</b>	<b>16,722</b>	<b>30,346</b>	<b>27,890</b>	<b>51,562</b>
<b>Total</b>	<b>\$ 128,929</b>	<b>\$ 17,935</b>	<b>\$ 31,542</b>	<b>\$ 27,890</b>	<b>\$ 51,562</b>

(1) As of September 30, 2009, we had approximately \$2.4 million in capital lease obligations (including the interest portion) associated with our equipment. All existing capital lease agreements as of September 30, 2009 are secured by the equipment financed, bear interest at rates between 4.99% and 10.36% and are due in monthly installments through 2012.

(2) On March 31, 2009, we amended our build-to-suit lease agreement to defer certain rental obligations in the aggregate amount of \$6.9 million, for a period of up to seventeen months. Under the terms of this amendment, we were obligated to repay the deferred amounts, including interest accruing at 12% during the deferral period, based on a timeline that could vary depending upon the occurrence of certain financing or collaborative transactions. In September 2009, we completed an underwritten public offering and received net proceeds of approximately \$101.5 million after deducting underwriting discounts and commissions and offering expenses. As a result of the above financing, we are obligated to pay our landlord \$3.7 million, or 50% of the deferred rental amounts, plus interest at 12%, within 45 days from the date of closing the public offering. We are obligated to pay the remaining deferred rental amounts, including related interest, of approximately \$4.5 million on

or before July 1, 2011. The accompanying schedule reflects our future rent obligations to our facilities lease after considering the effects of the above financing.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk**

During the nine months ended September 30, 2009, there were no material changes to our market risk disclosures as set forth in Part II, Item 7A, Quantitative and Qualitative Disclosures About Market Risk, of our Annual Report on Form 10-K for the year ended December 31, 2008.

**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 Securities Exchange Act of 1934, as amended), our chief executive officer and chief financial officer have concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective.

Table of Contents

*Changes in Internal Controls.* There were no changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2009 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**

On February 6, 2009, a purported securities class action lawsuit was commenced in the United States District Court for the Northern District of California, naming as defendants us and certain of our officers, directors and underwriters for our February 2008 stock offering. An additional purported securities class action lawsuit containing similar allegations was subsequently filed in the United States District Court for the Northern District of California on February 20, 2009. By order of the Court dated March 19, 2009, the two lawsuits were consolidated into a single action. On April 7, 2009, Inter-Local Pension Fund GCC/IBT filed a motion for appointment as lead plaintiff in the case, and for appointment of its counsel as lead counsel. On June 9, 2009, the Court issued an order naming the Inter-Local Pension Fund GCC/IBT as lead plaintiff and Coughlin Stoia as lead counsel. The lead plaintiff filed an amended complaint on July 24, 2009. The lawsuit alleges violations of the Securities Act of 1933 and the Securities Exchange Act of 1934 in connection with allegedly false and misleading statements made by us related to the results of the Phase 2a clinical trial of our product candidate R788. The plaintiffs seek damages, including rescission or rescissory damages for purchasers in the stock offering, an award of their costs and injunctive and/or equitable relief for purchasers of our common stock during the period between December 13, 2007 and February 9, 2009, including purchasers in the stock offering. We filed a motion to dismiss these claims on September 8, 2009, and a hearing on that motion is set for December 4, 2009. It is possible that additional suits will be filed with respect to these same matters and also naming us and/or our officers and directors as defendants. If any such additional suits are filed in the same court, we believe that they would be consolidated into the consolidated action.

We believe that we have meritorious defenses and intend to defend the lawsuit vigorously. This lawsuit and any other related 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 the litigation is necessarily uncertain, and we could be forced to expend significant resources in the defense of this lawsuit, and we may not prevail.

### **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*

## Edgar Filing: RIGEL PHARMACEUTICALS INC - Form 10-Q

*made in this Quarterly Report on Form 10-Q and those we may make from time to time. If any of the following risks actually occurs, our business, financial condition and operating results could be harmed. The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties not presently known to us, or that we currently see as immaterial, may also harm our business. We have marked with an asterisk (\*) those risk factors below that reflect a substantive change from the risk factors included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 27, 2009.*

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

We have consumed substantial amounts of capital to date, and our operating expenditures are expected to increase over the next several years as we continue our research and development activities, including preclinical studies and clinical trials.

We believe that our existing capital resources will be sufficient to support our current and projected funding requirements through at least the next 12 months. This estimate does not include any costs that we may incur in connection with a potential Phase 3 clinical trial evaluating R788 in RA patients, nor does this estimate include any potential payments that we may receive in connection with a potential collaboration covering the development of R788 for the treatment of RA. In addition, we have based this estimate on



Table of Contents

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 the development of our product candidates and other research and development activities, including risks and uncertainties that could impact the rate of progress of our development activities, we are unable to estimate with certainty the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials and other research and development activities.

For the foreseeable future, our operations will require significant additional funding, in large part due to our research and development expenses, future preclinical and clinical-testing costs, and the absence of any revenues from product sales. The amount of future funds needed will depend largely on the timing and structure of potential future collaborations, including in particular with respect to R788. We anticipate that we will enter into a collaboration agreement with respect to R788 in the first half of 2010, but we may not be able to do so on acceptable terms, or at all. Unless and until we are able to generate a sufficient amount of product revenue, 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 interest income earned on the investment of our cash balances and short-term investments. With the exception of milestone and royalty payments that we may receive under our existing collaborations, we do not currently have any commitments for future funding. We do not know whether additional financing will be available when needed, or that, if available, we will obtain financing on reasonable terms.

To the extent we raise additional capital by issuing equity securities, our stockholders could at that time experience substantial dilution. Any debt financing that we are able to obtain 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 relinquish some rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us

**Our future funding requirements will depend on many uncertain factors.\***

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

- our ability to establish new collaborations and the terms thereof;
- the progress and success of clinical trials and preclinical activities (including studies and manufacture of materials) of our product candidates conducted by us or our collaborative partners or licensees;
- the progress of research programs carried out by us;
- any changes in the breadth of our research and development programs;

## Edgar Filing: RIGEL PHARMACEUTICALS INC - Form 10-Q

- our ability to meet the milestones identified in our collaborative agreements that trigger payments to us from our collaboration partners;
- the progress of the research and development efforts of our collaborative partners;
- our ability to acquire or license other technologies or compounds that we 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 intellectual property rights;
- the costs and timing of regulatory approvals and filings by us and our collaborators; and
- expenses associated with the pending and potential additional related purported securities class action lawsuits, as well as any unforeseen litigation.

Insufficient funds may require us to delay, scale back or eliminate some or all of our research and 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.

Table of Contents

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

Due in large part to the significant research and development expenditures required to identify and validate new product candidates and pursue our development efforts, we have not been profitable and have incurred operating losses each year since we were incorporated in June 1996. The extent of our future losses and the timing of potential profitability are highly uncertain, and we may never achieve profitable operations. We incurred net losses of approximately \$86.5 million for the nine months ended September 30, 2009, \$132.3 million for the year ended December 31, 2008 and \$74.3 million for the year ended December 31, 2007. Currently, our only potential source of revenues is research and development milestone and royalty payments pursuant to our collaboration arrangements. We have not derived any revenues from these sources since 2007, and do not know whether we will recognize any additional revenues from our existing collaboration arrangements. Any future revenues that we receive may be insufficient to generate profitable operations. As of September 30, 2009, we had an accumulated deficit of approximately \$588.2 million. We expect to incur losses for at least the next several years and expect that these losses could increase as we expand our research and development activities and incur significant clinical and testing costs.

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

At the present time, the majority of our operations are in various stages of drug identification and development. We currently have four product compounds in the clinical testing stage: one with indications for RA, ITP, B-cell lymphoma, T-cell lymphoma, and certain solid tumors, which is proprietary to our company; one which has completed Phase 1 safety testing and is intended for psoriasis and possible topical applications, which is proprietary to our company; one with six indications for oncology, which is subject to a collaboration agreement with Merck Serono S.A., or Merck Serono; and one in Phase 1b testing and intended for allergic asthma, which is subject to a collaboration agreement with Pfizer, Inc., or Pfizer. 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, and we do not expect any drugs resulting from our research to be commercially available for several years, if at all.

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, obtaining regulatory approvals, maintaining regulatory compliance, manufacturing, competition and costs and expenses that may exceed current estimates. For example, in our recently completed *TASKi2* and *TASKi3*, two Phase 2b clinical trials for R788 in RA, the most common clinically meaningful drug-related adverse events noted were diarrhea and hypertension. In both of our *TASKi2* and *TASKi3* Phase 2b clinical trials, a meaningfully higher percentage of patients in the R788 treatment groups had blood pressure medication adjusted or initiated during the course of the clinical trials as compared to the placebo group. In larger future clinical trials, we may discover additional side effects and/or higher frequency of side effects than those observed in completed clinical trials. If approved by the U.S. Food and Drug Administration, or the FDA, the side effect profile of R788 may also result in a narrowly approved indication for use of the product, especially in light of other drugs currently available to treat RA, dependent on the safety profile of R788 relative to those drugs.

The results of preliminary and mid-stage studies do not necessarily predict clinical or commercial success, and larger later-stage clinical trials may fail to confirm the results observed in the previous studies. 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 different patient population, which may limit the potential market for that product candidate. For example, R788 produced significant clinical improvement in RA patients who had failed to respond to methotrexate alone in our *TASKi2* Phase 2b clinical trial, but our *TASKi3* Phase 2b clinical trial failed to meet its efficacy endpoints in RA patients who had failed to respond to at least one biologic treatment. In addition, if we were to repeat either of the *TASKi2* and *TASKi3* Phase 2b clinical trials, any such additional trials may not confirm the results observed in the original trials. As an additional example, our Phase 2 clinical trial for ITP was conducted in highly refractory patients, as opposed to

## Edgar Filing: RIGEL PHARMACEUTICALS INC - Form 10-Q

treatment-naive patients. If efficacy is not demonstrated among treatment-naive patients, any approved indication for ITP will be limited to a subset of the patient population. Furthermore, we plan to continue to conduct corporate partnership discussions with respect to R788. If we are able to enter into a collaboration for R788 and initiate a Phase 3 clinical trial evaluating R788 in RA patients, the Phase 3 clinical trial may not show R788 to be safe and effective for the treatment of RA patients. Finally, with respect to our own compounds in development, we have established anticipated timelines with respect to the initiation or completion of clinical studies based on existing knowledge of the compound. However, we cannot provide assurance that we will meet any of these timelines for clinical development.

Because of the uncertainty of whether the accumulated preclinical evidence (pharmacokinetic, 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.

Table of Contents

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

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 face the risks that:

- the product candidate may not prove to be effective;
- we may discover that a product candidate may cause harmful side effects;
- the results may not replicate the results of earlier, smaller trials;
- we or the FDA or similar foreign regulatory authorities may suspend the trials;
- the results may not be statistically significant;
- patient recruitment may be slower than expected;
- patients may drop out of the trials; and
- regulatory requirements may change.

We do not know whether we, or any of our collaborative partners, 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. Moreover, we or our collaborative partners or regulators may decide to discontinue development of any or all of these projects at any time for commercial, scientific or other reasons.

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

Significant delays in clinical testing could materially impact our product development costs and timing. We do not know whether planned clinical trials will begin on time, will need to be halted or redesigned or will be completed on schedule, or at all. For example, we do not expect to initiate Phase 3 clinical trials for R788 in RA prior to entering into a collaboration agreement with a third party for R788. Accordingly, the timing of Phase 3 clinical trials for R788 in RA is dependent on our ability to enter into such a collaboration agreement, and, if entered into, the terms of such collaboration agreement, including those governing the design of the clinical trial, as well as the amount and timing of resources that a collaborative partner devotes to R788. In addition, 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 study 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 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. While we have not yet experienced delays that have materially impacted our clinical trials or product development costs, delays of this sort could occur for the reasons identified above or other reasons. If we have delays in testing 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.

Table of Contents

**We lack the capability to manufacture compounds for development and rely on third parties to manufacture our product candidates, and we may be unable to obtain required material 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 product candidates for clinical testing, including R788. For each clinical trial of our unpartnered product candidates, we rely on a sole manufacturer for the active pharmaceutical ingredients, as well as various manufacturers to manufacture starting components, excipients and formulated drug products. We rely on manufacturers to produce and deliver all of the materials required for our clinical trials, and many of our preclinical efforts, on a timely basis and to comply with applicable regulatory requirements, including the FDA's current Good Manufacturing Practices, or cGMP. In addition, we rely on our suppliers to deliver sufficient quantities of materials produced under cGMP conditions to enable us to conduct planned preclinical studies and clinical trials.

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. 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. 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, or IND, applications and/or the initiation of clinical trials that we have currently planned.

Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration, and other federal and state 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 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, any of which could significantly and adversely affect our business.

**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 our ability to enter into additional collaborative agreements with third parties, including in particular with respect to R788, and to maintain the agreements we currently have in place. 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, including R788, 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, most of our revenues have been related to the research 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 partially offset by corresponding research costs. Following the completion of the research phase of each collaborative agreement, additional revenues may come only from milestone payments and royalties, which may not be paid, if at all, until some time well into the future. This risk is heightened due to the fact that unsuccessful research efforts may preclude us from receiving any milestone 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 milestone payments from our collaborations with Janssen Pharmaceutica N.V., a division of Johnson & Johnson, Novartis Pharma AG, or Novartis, Daiichi Pharmaceuticals Co., Ltd., or Daiichi, Merck & Co., Inc., or Merck, Merck Serono and Pfizer. Under many agreements, however, milestone payments may not be earned until the collaborator has advanced product candidates into clinical testing, which may never occur or may not occur until some time well into the future. For example, we have not received any milestone payments from our collaborators since 2007. 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.



Table of Contents

Our business requires us to generate meaningful revenue from royalties and licensing agreements. To date, we have not received any revenue from royalties for the commercial sale of drugs, and we do not know when we will receive any such revenue, if at all. Likewise, other than in connection with our collaborations, we have not licensed any lead compounds or drug development candidates to third parties, and we do not know whether any such license will be entered into on acceptable terms in the future, if at all.

**If our corporate collaborations or license agreements are unsuccessful, 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 in the future. We rely on these arrangements for not only financial resources, but also for expertise that we expect to need 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 third parties with which we collaborate, if any, will dedicate sufficient resources or if any development or commercialization efforts by third parties will be successful. 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 milestone payments, and we would not receive any royalties associated with such compound or product. 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.

The research phase of our collaboration with Johnson & Johnson ended in 2003, and the research phases conducted at our facilities under our broad collaboration with Novartis ended in 2004. The research phase of our collaboration agreement with Daiichi ended in 2005. In 2004, we signed a new collaboration agreement with Merck, and the research phase of this collaboration ended in May 2007. In 2005, we signed a new collaboration agreement with Pfizer, and the research phase of this collaboration ended in February 2007. Our collaboration agreement with Merck Serono, entered into in 2005, does not include a research phase. 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 and royalty rights with respect to drugs developed from certain derivative compounds, any such payments or royalty rights may be at reduced rates, and disputes may arise over the application of derivative payment provisions to such drugs, and we may not be successful in such disputes.

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.**

## Edgar Filing: RIGEL PHARMACEUTICALS INC - Form 10-Q

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.

Table of Contents

**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. We have over 110 pending patent applications and over 155 issued patents in the United States as well as numerous pending corresponding foreign patent applications. In the future, our patent position might be highly uncertain and involve complex legal and factual questions. For example, we may be involved in interferences before the United States Patent and Trademark Office. Interferences are complex and expensive legal proceedings and there is no assurance we will be successful in any such proceedings. An interference could result in our losing our patent rights and/or our freedom to operate and/or require us to pay significant royalties. 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 ensure 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; or
  
- the patents of others will not have a negative effect on our ability to do business.

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

We are a party to certain in-license agreements that are important to our business, and we generally do not control the prosecution of in-licensed technology. Accordingly, we are unable to exercise the same degree of control over this intellectual property as we exercise over our internally-developed technology. Moreover, some of our academic institution licensors, research collaborators and scientific advisors have rights to publish data and information in which we have rights. If we cannot maintain the confidentiality of our technology and other confidential information in connection with our collaborations, our ability to receive patent protection or protect our proprietary information may otherwise be impaired. In addition, some of the technology we have licensed relies on patented inventions developed using U.S. government resources. The U.S. government retains certain rights, as defined by law, in such patents, and may choose to exercise such rights. Certain of our in-licenses may be terminated if we fail to meet specified obligations. If we fail to meet such obligations and any of our licensors exercise their termination rights, we could lose our rights under those agreements. If we lose any of our rights, it may adversely affect the way we conduct our business. In addition, because certain of our licenses are sublicenses, the actions of our licensors may affect our rights under those licenses.

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

Our success will depend, in part, on our ability to operate without infringing or misappropriating the proprietary rights of others. There are many issued patents and patent applications filed by third parties relating to products or processes that are similar or identical to our licensors or ours, and others may be filed in the future. There can be no assurance that our activities, or those of our licensors, will not infringe patents owned by 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;

Table of Contents

- 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.

**The restructuring of our research programs could result in management distractions, operational disruptions and other difficulties.**

In February 2009, we announced that we cut our research programs in virology and oncology, as well as terminated certain related development and administrative staff, which resulted in the dismissal of 36 employees, or approximately 20% of our workforce. Employees whose positions were eliminated in connection with this reduction may seek future employment with our competitors. Although all employees are required to sign a confidentiality agreement with us at the time of hire, we cannot assure you that the confidential nature of our proprietary information will be maintained in the course of such future employment. Any additional restructuring efforts could divert the attention of our management away from our operations, harm our reputation and increase our expenses. We cannot assure you that we will not undertake additional restructuring activities, that any of our restructuring efforts will be successful, or that we will be able to realize the cost savings and other anticipated benefits from our previous or future restructuring plans. In addition, if we reduce our workforce further in the future, it may adversely impact our ability to continue to develop our product candidates.

**If we are unable to obtain regulatory approval to market products in the United States and foreign jurisdictions, we will not be permitted to commercialize products from our research and development.\***

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

Before commencing clinical trials in humans in the United States, we, or our collaborative partners, will need to submit and receive approval from the FDA of an IND. 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 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, 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 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

Table of Contents

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 ensure that any compound developed by us, alone or with others, will prove to be safe and efficacious in clinical trials and will meet all of the applicable regulatory requirements needed to receive marketing approval.

Outside the United States, our ability, or that of our collaborative partners, to market a product is contingent upon receiving a marketing authorization from the appropriate regulatory authorities. This foreign regulatory approval process typically includes all of the risks and costs associated with FDA approval described above and may also include additional risks and costs.

**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. We face, and will continue to face, intense competition from pharmaceutical and biotechnology companies, as well as from academic and research institutions and government agencies, both in the United States and abroad. Some of these competitors are pursuing the development of pharmaceuticals that target the same diseases and conditions as our research programs. Our major competitors include fully integrated pharmaceutical companies that 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;
- 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 and secure sufficient capital resources for the expected substantial time period between technological conception and commercial sales of products based upon our technology. The failure by any of our collaborators or us in any of those areas may prevent the successful commercialization of our potential drug targets.

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

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

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



Table of Contents

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

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

**Our ability to generate revenues will be diminished if our collaborative partners fail to obtain acceptable prices or an adequate level of reimbursement for products from third-party payors or government agencies.**

The drugs we hope to develop may be rejected by the marketplace due to many factors, including cost. Our ability to commercially exploit a drug may be limited due to the continuing efforts of government and third-party payors to contain or reduce the costs of health care through various means. For example, in some foreign markets, pricing and profitability of prescription pharmaceuticals are subject to government control. In the United States, we expect that there will continue to be a number of federal and state proposals to implement similar government control. In addition, increasing emphasis on managed care in the United States will likely continue to put pressure on the pricing of pharmaceutical products. Cost control initiatives could decrease the price that any of our collaborators would receive for any products in the future. Further, cost control initiatives could adversely affect our collaborators' ability to commercialize our products and our ability to realize royalties from this commercialization.

Our ability to commercialize pharmaceutical products with collaborators may depend, in part, on the extent to which reimbursement for the products will be available from:

- government and health administration authorities;
- private health insurers; and
- other third-party payors.

Significant uncertainty exists as to the reimbursement status of newly-approved healthcare products. Third-party payors, including Medicare, are challenging the prices charged for medical products and services. Government and other third-party payors increasingly are attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new drugs and by refusing, in some cases, to provide

coverage for uses of approved products for disease indications for which the FDA has not granted labeling approval. Third-party insurance coverage may not be available to patients for any products we discover and develop, alone or with collaborators. If government and other third-party payors do not provide adequate coverage and reimbursement levels for our products, the market acceptance of these products may be reduced.

**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 entail an inherent risk of product liability. 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. 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.

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

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

Table of Contents

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

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

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

Our research and development activities involve the controlled use of potentially harmful biological materials as well as hazardous materials, chemicals and various radioactive compounds. We cannot completely eliminate the risk of accidental contamination or injury from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for damages that result, 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 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.

**Future interest income and value of our investments may be impacted by further declines in interest rates and the broader effects of the recent turmoil in the global credit markets.**

Recently, the credit markets and the financial services industry have been experiencing a period of unprecedented turmoil and upheaval. As a result of this turmoil, the interest paid on certain of our investments may decrease and the value of certain securities we hold may decline in the future, which could negatively affect our financial condition, cash flow and reported earnings.

**We have been named a defendant in a purported securities class action lawsuit. This, and potential similar or related litigation, could result in substantial damages and may divert management's time and attention from our business.\***

On February 6, 2009, a purported securities class action lawsuit was commenced in the United States District Court for the Northern District of California, naming as defendants us, certain of our officers and directors, and the underwriters for our February 2008 stock offering. An additional purported securities class action lawsuit containing similar allegations was subsequently filed in the United States District Court for the Northern District of California on February 20, 2009. By order of the Court dated March 19, 2009, the two lawsuits were consolidated into a single action. On June 9, 2009, the Court issued an order naming the Inter-Local Pension Fund GCC/IBT as lead plaintiff. The lead plaintiff filed an amended complaint on July 24, 2009. The lawsuit alleges violations of the Securities Act of 1933 and the Securities Exchange Act of 1934 in connection with allegedly false and misleading statements made by us related to the results of the Phase 2a clinical trial of our product candidate R788. The plaintiff seeks damages, including rescission or rescissory damages for purchasers in the stock offering, an award of their costs and injunctive and/or equitable relief for purchasers of our common stock during the period between December 13, 2007 and February 3, 2009, including purchasers in the February 2008 stock offering. We filed a motion to dismiss these claims on September 8, 2009, and a hearing on that motion is set for December 4, 2009. It is possible that additional suits will be filed with respect to these same matters and also naming us and/or our officers and directors as defendants. If any such additional suits are filed in the same court, we believe that they would be consolidated into the consolidated action.

Table of Contents

We believe that we have meritorious defenses and intend to defend the lawsuit vigorously. This lawsuit and any other related 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 the litigation is necessarily uncertain, and we could be forced to expend significant resources in the defense of this suit, 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 the litigation. We are not currently able to estimate the possible cost to us from this matter, as this lawsuit is currently at an early stage and we cannot be certain how long it may take to resolve this matter or the possible amount of any damages that we may be required to pay. We have not established any reserves for any potential liability relating to this lawsuit. 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 this action could result in the payment of substantial damages, or possibly fines, and could have a material adverse effect on our cash flow, results of operations and financial position. In addition, the uncertainty of the currently pending litigation could lead to increased volatility in our stock price.

**Our stock price may be volatile, and our stockholders' investment in our 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:

- our ability to establish new collaborations and the terms thereof;
- the progress and success of clinical trials and preclinical activities (including studies and manufacture of materials) of our product candidates conducted by us or our collaborative partners or licensees;
- the receipt or failure to receive the additional funding necessary to conduct our business;
- selling by large stockholders;
- presentations of detailed clinical trial data at medical and scientific conferences and investor perception thereof;
- announcements of technological innovations or new commercial products by our competitors or us;
- developments concerning proprietary rights, including patents;

- developments concerning our collaborations;
- publicity regarding actual or potential medical results relating to products under development by our competitors or us;
- regulatory developments in the United States and foreign countries;
- litigation;
- economic and other external factors or other disaster or crisis; and
- period-to-period fluctuations in financial results.

**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 may need to raise 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. If we or our stockholders sell substantial amounts of our common stock (including shares issued upon the exercise of options and warrants) 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.

Table of Contents

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

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

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

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

**Item 6. Exhibits**

## Edgar Filing: RIGEL PHARMACEUTICALS INC - Form 10-Q

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.

<b>Exhibit Number</b>	<b>Description of Document</b>
3.1	Amended and Restated Certificate of Incorporation. (1)
3.2	Amended and Restated Bylaws. (2)
4.1	Form of warrant to purchase shares of common stock. (3)
4.2	Specimen Common Stock Certificate. (4)
4.3	Warrant issued to HCP BTC, LLC for the purchase of shares of common stock. (5)
10.7A	Amendment No. Two to Build-to-Suit Lease between the Company and Slough BTC, LLC, dated January 31, 2005.
10.7B	Amendment No. Three to Build-to-Suit Lease between the Company and Slough BTC, LLC dated July 24, 2006.
15.1	Letter regarding unaudited interim financial information.
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).

- 
- (1) Filed as an exhibit to Rigel s Current Report on Form 8-K filed on June 24, 2003 and incorporated herein by reference.
  - (2) Filed as an exhibit to Rigel s Current Report on Form 8-K filed on February 2, 2007 and incorporated herein by reference.
  - (3) Filed as an exhibit to Rigel s Registration Statement on Form S-1 (No. 333-45864), as amended, and incorporated herein by reference.
  - (4) Filed as an exhibit to Rigel s Current Report on Form 8-K (No. 000-29889) filed on June 24, 2003, and incorporated herein by reference.
  - (5) Filed as an exhibit to Rigel s Quarterly Report on Form 10-Q (No. 000-29889) filed on May 5, 2009, and incorporated herein by reference.



**Table of Contents**



**SIGNATURES**



Edgar Filing: RIGEL PHARMACEUTICALS INC - Form 10-Q

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/ JAMES M. GOWER  
James M. Gower  
Chief Executive Officer  
(Principal Executive Officer)

Date: November 3, 2009

By: /s/ RYAN D. MAYNARD  
Ryan D. Maynard  
Vice President and Chief Financial Officer  
(Principal Financial and Accounting Officer)

Date: November 3, 2009

**Table of Contents**



**INDEX TO EXHIBITS**



Edgar Filing: RIGEL PHARMACEUTICALS INC - Form 10-Q

<b>Exhibit Number</b>	<b>Description of Document</b>
3.1	Amended and Restated Certificate of Incorporation. (1)
3.2	Amended and Restated Bylaws. (2)
4.1	Form of warrant to purchase shares of common stock. (3)
4.2	Specimen Common Stock Certificate. (4)
4.3	Warrant issued to HCP BTC, LLC for the purchase of shares of common stock. (5)
10.7A	Amendment No. Two to Build-to-Suit Lease between the Company and Slough BTC, LLC, dated January 31, 2005.
10.7B	Amendment No. Three to Build-to-Suit Lease between the Company and Slough BTC, LLC dated July 24, 2006.
15.1	Letter regarding unaudited interim financial information.
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).

- 
- (1) Filed as an exhibit to Rigel's Current Report on Form 8-K filed on June 24, 2003 and incorporated herein by reference.
  - (2) Filed as an exhibit to Rigel's Current Report on Form 8-K filed on February 2, 2007 and incorporated herein by reference.
  - (3) Filed as an exhibit to Rigel's Registration Statement on Form S-1 (No. 333-45864), as amended, and incorporated herein by reference.
  - (4) Filed as an exhibit to Rigel's Current Report on Form 8-K (No. 000-29889) filed on June 24, 2003, and incorporated herein by reference.
  - (5) Filed as an exhibit to Rigel's Quarterly Report on Form 10-Q (No. 000-29889) filed on May 5, 2009, and incorporated herein by reference.