

RIGEL PHARMACEUTICALS INC

Form 10-Q

May 05, 2009

[Table of Contents](#)

## **UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**FORM 10-Q**

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

**FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2009**

**OR**

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

**FOR THE TRANSITION PERIOD FROM        TO**

**Commission File Number 0-29889**

---

**Rigel Pharmaceuticals, Inc.**

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 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. (Check one):

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 April 30, 2009, there were **36,700,860** 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 MARCH 31, 2009**





**INDEX**



|  | <b>Page</b> |
|--|-------------|
| <b><u>PART I</u></b>   |             |
| <b><u>FINANCIAL INFORMATION</u></b>  |             |
| <b><u>Item 1.</u></b>  |             |
| <u>Condensed Financial Statements</u>  | 3           |
| <u>Condensed Balance Sheets March 31, 2009 (Unaudited) and December 31, 2008</u>                 | 3           |
| <u>Condensed Statements of Operations (Unaudited) three months ended March 31, 2009 and 2008</u> | 4           |
| <u>Condensed Statements of Cash Flows (Unaudited) three months ended March 31, 2009 and 2008</u> | 5           |
| <u>Notes to Condensed Financial Statements (Unaudited)</u>                                       | 6           |
| <u>Report of Independent Registered Public Accounting Firm</u>                                   | 13          |
| <b><u>Item 2.</u></b>  |             |
| <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>     | 14          |
| <b><u>Item 3.</u></b>  |             |
| <u>Quantitative and Qualitative Disclosures About Market Risk</u>                                | 24          |
| <b><u>Item 4.</u></b>  |             |
| <u>Controls and Procedures</u>   | 24          |
| <b><u>PART II</u></b>  |             |
| <b><u>OTHER INFORMATION</u></b>  | 24          |
| <b><u>Item 1.</u></b>  |             |
| <u>Legal Proceedings</u>   | 24          |
| <b><u>Item 1A.</u></b>   |             |
| <u>Risk Factors</u>  | 25          |
| <b><u>Item 2.</u></b>  |             |
| <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>                               | 36          |
| <b><u>Item 6.</u></b>  |             |
| <u>Exhibits</u>  | 37          |
| <b><u>Signatures</u></b>   | 38          |

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>March 31,<br/>2009<br/>(unaudited)</b> | <b>December 31,<br/>2008 (1)</b> |
|---|---|----------------------------------|
| <b>Assets</b>   |   |                                  |
| Current assets:   |   |                                  |
| Cash and cash equivalents   | \$ 36,729                                 | \$ 46,005                        |
| Available-for-sale securities   | 68,082                                    | 88,472                           |
| Prepaid expenses and other current assets   | 3,187                                     | 3,610                            |
| Total current assets  | 107,998                                   | 138,087                          |
| Property and equipment, net   | 3,258                                     | 3,567                            |
| Other assets  | 2,770                                     | 2,204                            |
|   | \$ 114,026                                | \$ 143,858                       |
| <b>Liabilities and stockholders equity</b>  |   |                                  |
| Current liabilities:  |   |                                  |
| Accounts payable  | \$ 6,790                                  | \$ 5,984                         |
| Accrued compensation  | 1,651                                     | 1,625                            |
| Other accrued liabilities   | 9,400                                     | 12,029                           |
| Deferred rent   | 634                                       | 3,174                            |
| Capital lease obligations   | 1,226                                     | 1,339                            |
| Total current liabilities   | 19,701                                    | 24,151                           |
| Long-term portion of capital lease obligations  | 1,730                                     | 2,053                            |
| Long-term portion of deferred rent  | 15,456                                    | 13,311                           |
| Other long-term liabilities   | 171                                       | 178                              |
| Commitments and contingencies   |   |                                  |
| Stockholders equity:  |   |                                  |
| Preferred stock, \$0.001 par value; 10,000,000 shares authorized; none issued and outstanding as of March 31, 2009 and December 31, 2008                                      |   |                                  |
| Common stock, \$0.001 par value; 100,000,000 shares authorized; 36,700,860 and 36,646,397 shares issued and outstanding on March 31, 2009 and December 31, 2008, respectively | 37  | 37                               |
| Additional paid-in capital  | 608,489                                   | 605,509                          |
| Accumulated other comprehensive income  | 141                                       | 396                              |
| Accumulated deficit   | (531,699)                                 | (501,777)                        |
| Total stockholders equity   | 76,968                                    | 104,165                          |
|   | \$ 114,026                                | \$ 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)

|  | Three Months Ended March 31, |             |
|--|------------------------------|-------------|
|  | 2009                         | 2008        |
| Contract revenues  | \$                           | \$          |
| Costs and expenses:  |                              |             |
| Research and development   | 24,538                       | 21,620      |
| General and administrative   | 4,603                        | 7,125       |
| Restructuring charges  | 1,141                        |             |
|  | 30,282                       | 28,745      |
| Loss from operations   | (30,282)                     | (28,745)    |
| Interest income  | 347                          | 1,530       |
| Interest expense   | (53)                         | (47)        |
| Loss before income taxes   | (29,988)                     | (27,262)    |
| Income tax benefit   | 66                           |             |
| Net loss   | \$ (29,922)                  | \$ (27,262) |
| Net loss per share, basic and diluted  | \$ (0.82)                    | \$ (0.79)   |
| Weighted average shares used in computing net loss per common share, basic and diluted | 36,699                       | 34,417      |

See Accompanying Notes.

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

|   | <b>Three Months Ended<br/>March 31,</b> |             |
|---|---|-------------|
|   | <b>2009</b>                             | <b>2008</b> |
| <b>Operating activities</b>   |   |             |
| Net loss  | \$ (29,922)                             | \$ (27,262) |
| Adjustments to reconcile net loss to net cash used in operating activities: |   |             |
| Depreciation and amortization   | 320                                     | 342         |
| Stock-based compensation expense  | 2,266                                   | 5,846       |
| Changes in assets and liabilities:  |   |             |
| Prepaid expenses and other current assets                                   | 423                                     | (951)       |
| Other assets  | 50                                      | 38          |
| Accounts payable  | 806                                     | (732)       |
| Accrued compensation  | 26                                      | (5,190)     |
| Other accrued liabilities   | (2,629)                                 | 974         |
| Deferred rent and other long-term liabilities                               | (402)                                   | (145)       |
| Net cash used in operating activities                                       | (29,062)                                | (27,080)    |
| <b>Investing activities</b>   |   |             |
| Purchases of available-for-sale securities                                  | (27,034)                                | (73,605)    |
| Maturities of available-for-sale securities                                 | 44,190                                  | 30,676      |
| Sale of available-for-sale securities                                       | 2,979                                   |             |
| Capital expenditures  | (11)                                    | (297)       |
| Net cash provided by (used in) investing activities                         | 20,124                                  | (43,226)    |
| <b>Financing activities</b>   |   |             |
| Proceeds from capital lease financings                                      |   | 219         |
| Payments on capital lease obligations                                       | (436)                                   | (316)       |
| Net proceeds from issuances of common stock                                 | 98                                      | 128,496     |
| Net cash (used in) provided by financing activities                         | (338)                                   | 128,399     |
| Net (decrease) increase in cash and cash equivalents                        | (9,276)                                 | 58,093      |
| Cash and cash equivalents at beginning of period                            | 46,005                                  | 44,503      |
| Cash and cash equivalents at end of period                                  | \$ 36,729                               | \$ 102,596  |
| <b>Supplemental disclosure of cash flow information</b>                     |   |             |
| Interest paid   | \$ 55                                   | \$ 45       |
| <b>Schedule of non cash transactions</b>                                    |   |             |
| Issuance of warrants with lease amendment                                   | \$ 616                                  | \$          |

See Accompanying Notes.





**Table of Contents**



**Rigel Pharmaceuticals, Inc.**

**Notes to Condensed Financial Statements**

**(unaudited)**



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

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 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. generally accepted accounting principles 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. generally accepted accounting principles for complete financial statements. Because all of the disclosures required by U.S. generally accepted accounting principles 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. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results could differ from these estimates.

### 3. Recent Accounting Pronouncements

On June 25, 2008, the Financial Accounting Standards Board, or FASB, ratified the consensus reached by the Emerging Issues Task Force, or EITF, on EITF Issue No. 07-5 *Determining Whether an Instrument (or Embedded Feature) is Indexed to an Entity's Own Stock*, or EITF 07-5. EITF 07-5 provides guidance on how to determine whether certain instruments or features were indexed to the company's own stock. EITF 07-5 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. We adopted EITF 07-5 on January 1, 2009 and concluded it had no material impact on our financial statements.

On December 12, 2007, the FASB ratified the consensus reached by the EITF on EITF Issue No. 07-1, *Accounting for Collaborative Arrangements*, or EITF 07-1. EITF 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. EITF 07-1 is effective for financial statements issued for fiscal years beginning after December 15, 2008 and will be applied retrospectively to all prior periods presented for all collaborative arrangements existing as of the effective date. We adopted EITF 07-1 on January 1, 2009 and concluded it had no material impact on our financial statements.



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

In September 2006, the FASB issued Statement of Financial Accounting Standards, or SFAS, No. 157, *Fair Value Measurements*, or SFAS No. 157. This standard defines fair value, establishes a framework for measuring fair value under U.S. generally accepted accounting principles, 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*, 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, 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.

Table of Contents**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<br>March 31, |       |      |       |
|--|---------------------------------|-------|------|-------|
|  | 2009                            |       | 2008 |       |
| Research and development               | \$                              | 1,425 | \$   | 3,092 |
| General and administrative             |                                 | 719   |      | 2,754 |
| Restructuring charges                  |                                 | 122   |      |       |
| Total stock-based compensation expense | \$                              | 2,266 | \$   | 5,846 |

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 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, 2008 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.

Under SFAS No. 123(R), *Accounting for Stock-Based Compensation*, 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.

- 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.

Table of Contents

- **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 months ended March 31, 2009 and 2008:

|                          | <b>Three Months Ended<br/>March 31,</b> |             |
|--------------------------|---|-------------|
|                          | <b>2009</b>                             | <b>2008</b> |
| Risk-free interest rate  | 1.8%                                    | 2.7%        |
| Expected term (in years) | 4.4                                     | 4.6         |
| Dividend yield           | 0.0%                                    | 0.0%        |
| Expected volatility      | 98.4%                                   | 93.2%       |

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 1,982,473 shares of common stock during the three months ended March 31, 2009, with a grant-date weighted average fair value of \$4.60 per share. We granted options to purchase 1,305,691 shares of common stock during the three months ended March 31, 2008, with a grant-date weighted average fair value of \$18.48 per share. As of March 31, 2009, there was approximately \$17.9 million of total unrecognized stock-based compensation cost, net of estimated forfeitures, related to unvested options granted under our stock option plans. At March 31, 2009, 2,589,743 shares of common stock were available for future grant under our equity incentive plans and options to purchase 54,463 shares were exercised during the three months ended March 31, 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 the weighted-average assumptions set forth on the following table. 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.

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

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 SFAS No. 123(R) to determine the incremental fair value associated with this ESPP reset and recognized the related stock-based compensation expense according to the FASB Technical Bulletin, or FTB, No. 97-1, *Accounting Under Statement 123 for Certain Employee Stock Purchase Plans with a Look-back Option*. The total incremental fair value for this ESPP reset was \$1,443,848, which will be recognized over the new twenty-four month offering period.

As of March 31, 2009, there were approximately 1,409,931 shares reserved for future issuance under the ESPP. The following table summarizes the weighted-average assumptions related to our ESPP for the three months ended March 31, 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.

|                          | Three Months Ended |       |
|--------------------------|--------------------|-------|
|                          | 2009               | 2008  |
| Risk-free interest rate  | 1.1%               | 2.1%  |
| Expected term (in years) | 1.3                | 1.2   |
| Dividend yield           | 0.0%               | 0.0%  |
| Expected volatility      | 112.0%             | 99.0% |

Table of Contents**6. Revenue Recognition**

We recognize revenue from our collaboration arrangements in accordance with Emerging Issues Task Force, or EITF, No. 07-1, *Accounting for Collaborative Arrangements*. Our revenue arrangements with multiple elements are evaluated under EITF No. 00-21, *Revenue Arrangements with Multiple Deliverables*, 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. Cash, Cash Equivalents and Available-For-Sale Securities**

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

|  | March 31,<br>2009 | December 31,<br>2008 |
|--|-------------------|----------------------|
| Checking account                           | \$ 904            | \$ 491               |
| Money market funds                         | 30,825            | 45,514               |
| U. S. treasury bills                       | 24,941            | 26,085               |
| Government-sponsored enterprise securities | 28,610            | 34,641               |
| Corporate bonds and commercial paper       | 19,531            | 27,746               |
|  | \$ 104,811        | \$ 134,477           |

Reported as:

Edgar Filing: RIGEL PHARMACEUTICALS INC - Form 10-Q

|                               |    |         |    |         |
|-------------------------------|----|---------|----|---------|
| Cash and cash equivalents     | \$ | 36,729  | \$ | 46,005  |
| Available-for-sale securities |    | 68,082  |    | 88,472  |
|                               | \$ | 104,811 | \$ | 134,477 |

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

|  | Amortized<br>Cost | Gross<br>Unrealized<br>Gains | Gross<br>Unrealized<br>Losses | Fair Value       |
|--|-------------------|------------------------------|-------------------------------|------------------|
| <b>March 31, 2009</b>                      |                   |                              |                               |                  |
| U. S. treasury bills                       | \$ 24,910         | \$ 31                        | \$                            | \$ 24,941        |
| Government-sponsored enterprise securities | 28,567            | 49                           | (6)                           | 28,610           |
| Corporate bonds and commercial paper       | 19,464            | 67                           |                               | 19,531           |
| <b>Total</b>                               | <b>\$ 72,941</b>  | <b>\$ 147</b>                | <b>\$ (6)</b>                 | <b>\$ 73,082</b> |

|  | Amortized<br>Cost | Gross<br>Unrealized<br>Gains | Gross<br>Unrealized<br>Losses | Fair Value       |
|--|-------------------|------------------------------|-------------------------------|------------------|
| <b>December 31, 2008</b>                   |                   |                              |                               |                  |
| 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           |
| <b>Total</b>                               | <b>\$ 88,076</b>  | <b>\$ 396</b>                | <b>\$</b>                     | <b>\$ 88,472</b> |

Table of Contents

*Available-for-sale Securities.* As of March 31, 2009, all of our cash equivalents and available-for-sale securities had maturities of less than one year. At March 31, 2009, our available-for-sale securities had a weighted average time to maturity of approximately 106 days. We have the ability to hold all investments as of March 31, 2009 to maturity.

At March 31, 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 March 31, 2009, a total of 8 individual securities were in an unrealized loss position for twelve months or less and were deemed to be temporary.

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):

| <b>March 31, 2009</b>                      | <b>Fair Value</b> |               | <b>Unrealized Losses</b> |            |
|--|-------------------|---------------|--------------------------|------------|
| Government-sponsored enterprise securities | \$                | 7,835         | \$                       | (6)        |
| Corporate bonds and commercial paper       |                   | 4,999         |                          |            |
| <b>Total</b>                               | <b>\$</b>         | <b>12,834</b> | <b>\$</b>                | <b>(6)</b> |

## 8. Fair Value

Under SFAS No. 157, 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.

Financial assets 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, defined by SFAS No. 157 and 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.



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

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, 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.

Table of Contents

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 March 31, 2009 |           |         |            |
|--|---|-----------|---------|------------|
|  | Level 1                                   | Level 2   | Level 3 | Total      |
| Money market fund                          | \$ 30,825                                 | \$        | \$      | \$ 30,825  |
| U. S. treasury bills                       |   | 24,941    |         | 24,941     |
| Government-sponsored enterprise securities |   | 28,610    |         | 28,610     |
| Corporate bonds and commercial paper       |   | 19,531    |         | 19,531     |
| Total                                      | \$ 30,825                                 | \$ 73,082 | \$      | \$ 103,907 |

***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 10 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 warrants in accordance with SFAS No. 123(R). The new warrants was categorized as level 3 under SFAS No. 157 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 warrants at March 31, 2009:

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

**9. 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. This measure was intended to

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

maintain our emphasis on active preclinical and clinical programs, while conserving our resources. Consequently, we recorded restructuring charges of \$1.1 million, including \$1.0 million of workforce reduction costs and \$122,000 of non-cash stock-based compensation expense as a result of the extension of the date the terminated employees had to exercise their vested options to December 31, 2008 rather than 90 days from termination date as is typically required under our equity incentive plan. At March 31, 2009, \$28,000 of the restructuring charges related to COBRA benefits for the remaining periods of 2009 were unpaid and classified under accrued compensation on the balance sheet.

Table of Contents

**10. 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. We consider accrued interest on the deferred amounts to be contingent rent payments and accordingly, recognize such amounts in rent expense as incurred. The amount of contingent rent expense we incurred in the first quarter of 2009 was approximately \$138,000. 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 SFAS No. 123(R) 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.

**11. 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 us and certain of our officers, directors and underwriters as defendants for our February 2008 stock offering. 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 a 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 its costs and injunctive and/or equitable relief for purchasers of our common stock during the period between December 13, 2007 and October 27, 2008, including purchasers in the 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. It is possible that additional suits will be filed, or allegations received from stockholders, with respect to these same matters and also naming us and/or our executive 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 cost 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 March 31, 2009, and the related condensed statements of operations and cash flows for the three-month periods ended March 31, 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 interim financial statements referred to above for them to be in conformity with U.S. 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  
May 1, 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 months ended March 31, 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 revenues that may be received from these 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. Our productivity has resulted in strategic collaborations with large pharmaceutical partners to develop and market our product candidates. We have product development programs in inflammatory/autoimmune diseases such as rheumatoid arthritis, thrombocytopenia and asthma, as well as in cancer.

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 \$29.9 million for the three months ended March 31, 2009, \$132.3 million in 2008 and \$74.3 million in 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 primarily through private and public offerings of our common stock. As of March 31, 2009, we had an accumulated deficit of approximately \$531.7 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.

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

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. 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 continue to pursue a collaboration partner for our lead product candidate, R788, prior to initiating Phase 3 clinical trials. We have engaged in discussions with various parties regarding such a partnership. At the present time, while we have parties who have indicated an interest in entering into a partnership for R788, we believe we will be able to negotiate a more attractive arrangement for us and our stockholders once we have the results from the two Phase 2b clinical trials of R788, *TASKi2* and *TASKi3*. Results from both of these clinical trials are expected to be available in July 2009.

Table of Contents

We will have to raise additional capital if we do not identify a collaboration partner for R788. 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.

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 and metabolic diseases. Our multiple product candidates in development are as follows:

- *R788 (fostamatinib disodium) Product Candidate for Rheumatoid Arthritis (RA).* R788 is our lead product candidate. It has a novel mechanism of action, inhibiting immunoglobulins G (IgG) receptor signaling in macrophages and B-cells. Previously, we studied R788 in a Phase 1, single center, double-blind, randomized, placebo-controlled, clinical trial evaluating the safety and pharmacokinetics of escalating single and multiple doses of R788. We also completed a Phase 2a clinical trial of R788 with 189 patients to evaluate its safety and pharmacokinetics in combination with methotrexate, a commonly prescribed treatment for RA. Results of this clinical trial suggested that there is not an adverse interaction between R788 and methotrexate.

In December 2007, we announced the results of a Phase 2a clinical trial of R788 in RA patients simultaneously receiving methotrexate, in which doses of 100 mg PO bid (orally, twice daily) and 150 mg PO bid of R788 produced statistically significant improvement in RA symptoms. The most common clinically meaningful adverse events noted in the clinical trial included dose-related neutropenia, mild elevations of liver function tests and gastrointestinal side effects. Dose reduction (to one-half the assigned dose by taking the drug once per day) was pre-specified in the protocol and contingent on neutrophil counts and/or liver function tests. Notably, a vast majority of the patients who had their doses reduced successfully completed the clinical trial with minimal safety issues.

In June 2008, we commenced two concurrent Phase 2b clinical trials of R788 in RA patients at a number of clinical research centers throughout the United States, Latin America, and Europe to evaluate the efficacy of R788 compared to placebo in distinct RA patient groups. The first Phase 2b clinical trial (*TASKi2*) is evaluating RA patients receiving 100 mg of R788 PO bid (orally, twice daily) or 150 mg of R788 PO qd (orally, once daily), compared with those receiving placebo, in a multi-center, randomized, double blind, placebo controlled, parallel dose study of R788 in patients who have failed to respond to methotrexate. The second Phase 2b clinical trial (*TASKi3*) is evaluating a group of RA patients receiving 100 mg of R788 PO bid, compared with a group receiving placebo, in a multi-center, randomized, double blind, placebo controlled, parallel dose study of R788 in patients who have failed at least one marketed biologic agent. The marketed biologic agents generally includes anti-tumor necrosis factor injectables commonly used to treat RA, but could include other therapies as well. The primary objectives for *TASKi2*



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

and *TASKi3* are to measure the efficacy of R788 at 6 months and 3 months, respectively, as determined by ACR20 scores (American College of Rheumatology responder rates showing a minimum of 20% improvement in RA symptoms and pain). Secondary objectives include comparing higher ACR response rates (ACR 50 and ACR 70), as well as DAS28 rates (Disease Activity Score including a 28-joint inspection), in addition to various safety measures. *TASKi3* will also include measurement of changes in bone morphology using MRI scans as a secondary measure.

Enrollment for the *TASKi2* clinical trial of R788 in patients with RA who previously failed to respond to methotrexate treatment was completed in December 2008, with 457 patients randomized. The smaller *TASKi3* clinical trial of R788 completed enrollment in March 2009, with 219 patients randomized. *TASKi3* is for RA patients who previously failed to respond to at least one marketed biologic treatment. Results from both of these clinical trials are expected to be available in July 2009. We expect that these results, involving approximately 670 additional patients, will substantially further the understanding of the potential of R788 and may therefore drive enhanced economics in a possible deal.

Table of Contents

The recently completed double-blind, double-dummy, randomized, positive and placebo-controlled parallel study of the effects of R788 on QT/QTc intervals in healthy subjects confirmed that R788 does not elicit a QT/QTc signal. Under a protocol pre-reviewed by the Food and Drug Administration (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 100mg bid of R788, a super dose of 300mg 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 100mg bid or the 300mg bid R788 dosage groups. As expected, the study found that participants in the moxifloxacin group experienced QT/QTc elevations.

- *R788 Product Candidate for Immune Thrombocytopenic Purpura (ITP).* Platelet destruction from ITP is mediated by IgG signaling, and R788 is a potent inhibitor of IgG signaling. In preclinical studies, R788 was shown to improve thrombocytopenia in an ITP mouse model. We recently 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 have further clarity on development priorities from a potential partner for R788.
- *R788 Product Candidate for B-Cell Lymphoma.* Research has shown that over activity of the signaling enzyme spleen tyrosine kinase, or 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. In December 2008, we reported that R788 is well-tolerated by B-cell Lymphoma patients and shows therapeutic benefit in patients suffering from diffuse large B-Cell lymphoma (DLBCL) and chronic lymphocytic leukemia/small lymphocytic lymphoma (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 NHL 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 (PTCL). The primary objective of the clinical trial is to assess the efficacy of R788, an orally bio-available Syk kinase inhibitor, 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 will be 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 8 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 (CT/PET) scans at baseline and CT scans of the disease-involved areas at 8 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 Systemic Lupus Erythematosus (SLE or Lupus).* Preclinical studies have shown that R788 is highly effective in a murine model of lupus. The initiation of a clinical trial in Lupus patients has been postponed until we have further clarity on development priorities from a potential partner for R788.

Table of Contents

- *R348 Product Candidate for Psoriasis and other immune disorders.* R348 is a potent and selective 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. Moving forward, we plan to focus on psoriasis and possible topical applications of R348 in conjunction with a collaboration partner.

- *R763 Product Candidate for Oncology.* R763/AS703569 is a potent, highly-selective, small-molecule inhibitor of aurora kinase. In October 2005, we signed a licensing agreement with 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 will evaluate two different treatment regimens in which R763/AS703569 will be 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, will be evaluated. We expect that Merck Serono will initiate a Phase 2 trial by the end of 2009.

- *R343 Product Candidate for Asthma.* In the first quarter of 2005, we announced a collaborative research and license agreement with 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 is focused on our preclinical small molecule compounds, which inhibit IgE receptor signaling in respiratory tract mast cells by blocking Syk, a novel drug target for respiratory diseases. Mast cells play important roles in both early and late phase allergic reactions, and Syk inhibitors could prevent both phases.

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 by that time. We expect that Pfizer will initiate a Phase 1b allergen challenge trial in 2009.

### **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:

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

- 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;
- Merck Serono, relating to our aurora kinase inhibitor program.

None of these collaborations currently provides us with regular research reimbursement. 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.

Table of Contents

**Recent Accounting Pronouncements**

On June 25, 2008, the Financial Accounting Standards Board, or FASB, ratified the consensus reached by the Emerging Issues Task Force, or EITF, on EITF Issue No. 07-5 *Determining Whether an Instrument (or Embedded Feature) is Indexed to an Entity's Own Stock*, or EITF 07-5. EITF 07-5 provides guidance on how to determine whether certain instruments or features were indexed to the company's own stock. EITF 07-5 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. We adopted EITF 07-5 on January 1, 2009 and concluded it had no material impact on our financial statements.

On December 12, 2007, the FASB ratified the consensus reached by the EITF on EITF Issue No. 07-1, *Accounting for Collaborative Arrangements*, or EITF 07-1. EITF 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. EITF 07-1 is effective for financial statements issued for fiscal years beginning after December 15, 2008 and will be applied retrospectively to all prior periods presented for all collaborative arrangements existing as of the effective date. We adopted EITF 07-1 on January 1, 2009 and concluded it had no material impact on our financial statements.

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

Our discussion and analysis of our financial condition and results of operations is based upon our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. 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 the research collaborations (i.e. amortization of upfront fees and certain milestone payments), investments, stock 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 in accordance with Emerging Issues Task Force, or EITF, No. 07-1, *Accounting for Collaborative Arrangements*. Our revenue arrangements with multiple elements are evaluated under EITF No. 00-21, *Revenue Arrangements with Multiple Deliverables*, 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.

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

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.

Table of Contents

*Stock-based Compensation*

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 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 completed and 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 the third parties are expensed at the time of purchase. Many of our estimates are based significantly or in part on information provided by the third parties. If such information were not reported properly, our research and development expense amounts could be misstated.

**Results of Operations**

**Three Months Ended March 31, 2009 and 2008**

**Revenues**

There were no contract revenues reported during the three months ended March 31, 2009 and 2008. We had no deferred revenue as of March 31, 2009. Our potential future revenues may include certain milestone payments from our current collaboration partners or new collaboration partners with whom we enter into agreements in the future.

**Research and Development Expenses**

**Three Months Ended**



Edgar Filing: RIGEL PHARMACEUTICALS INC - Form 10-Q

|   | 2009      | March 31,<br>2008 | Aggregate Change |
|---|-----------|-------------------|------------------|
|   |           | (in thousands)    |                  |
| <i>Research and development expenses</i>  | \$ 24,538 | \$ 21,620         | \$ 2,918         |
| <i>Stock-based compensation expense included in research and development expenses</i> | 1,425     | 3,092             | (1,667)          |

The increase in research and development expenses for the three months ended March 31, 2009, compared to the same period in 2008, was primarily due to an increase in clinical costs, partially offset by the combination of a decrease in stock-based compensation expense as discussed under *Stock-Based Compensation* below and a decrease in bonus expense as we did not book a bonus accrual in the first quarter of 2009. The increase in clinical costs was primarily attributable to increased costs associated with our two Phase 2b clinical trials (*TASKi2* and *TASKi3*), as well as the related extension trials in RA patients and manufacturing R788 material to be used in these clinical trials.

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. 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. Our research and development expenditures currently 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**General and Administrative Expenses**

|   | Three Months Ended<br>March 31, |                |                  |
|---|---------------------------------|----------------|------------------|
|   | 2009                            | 2008           | Aggregate Change |
|   |                                 | (in thousands) |                  |
| <i>General and administrative expenses</i>  | \$ 4,603                        | \$ 7,125       | \$ (2,522)       |
| <i>Stock-based compensation expense included in general and administrative expenses</i> | 719                             | 2,754          | (2,035)          |

The decrease in general and administrative expenses for the three months ended March 31, 2009, as compared to the same period in 2008, was primarily attributable to the decrease in stock-based compensation expense as discussed under "Stock-Based Compensation" below and a decrease in bonus expense as we did not book a bonus accrual in the first quarter of 2009. Due to the purported securities class action lawsuit recently filed against us, we expect that our legal expenses will increase in 2009, as we will vigorously defend the lawsuit.

**Restructuring Charges**

|   | Three Months Ended<br>March 31, |                |                  |
|---|---------------------------------|----------------|------------------|
|   | 2009                            | 2008           | Aggregate Change |
|   |                                 | (in thousands) |                  |
| <i>Restructuring Charges</i>  | \$ 1,141                        | \$ 1,141       | \$ 1,141         |
| <i>Stock-based compensation expense included in restructuring charges</i> | 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 and \$122,000 of non-cash stock-based compensation expense as a result of the extension of the option cancellation date for terminated employees to December 31, 2008 rather than 90 days from termination date.

**Stock-Based Compensation**

|   | Three Months Ended<br>March 31, |                |                  |
|---|---------------------------------|----------------|------------------|
|   | 2009                            | 2008           | Aggregate Change |
|   |                                 | (in thousands) |                  |
| <b>Stock-based compensation expense from:</b> |                                 |                |                  |
| <i>Officer, director and employee options</i> | \$ 2,266                        | \$ 5,733       | \$ (3,467)       |
| <i>Consultant options</i>                     |                                 | 113            | (113)            |
| <b>Total</b>                                  | \$ 2,266                        | \$ 5,846       | \$ (3,580)       |

The decrease in stock-based compensation expense for the three months ended March 31, 2009, as compared to the same period in 2008, was primarily due to the higher valuation of options granted in the first quarter of 2008 and the full recognition of most of the expense associated with those options as of the end of 2008. The decrease was also due to the fact that a majority of the options were being granted at the end of the first quarter of 2009 and had only vested for one day. As a result, the 2009 option grants did not result in a significant recognition of stock-based compensation expense in the first quarter of 2009.

Table of Contents**Interest Income**

|                        | <b>Three Months Ended<br/>March 31,</b> |             |                         |
|------------------------|---|-------------|-------------------------|
|                        | <b>2009</b>                             | <b>2008</b> | <b>Aggregate Change</b> |
|                        | <b>(in thousands)</b>                   |             |                         |
| <i>Interest income</i> | \$ 347                                  | \$ 1,530    | \$ (1,183)              |

Interest income results from our interest-bearing cash and investment balances. The decrease in interest income for the three months ended March 31, 2009, as compared to the same period in 2008, was due to a lower cash balance and lower interest rates earned on our investments in 2009.

**Interest Expense**

|                         | <b>Three Months Ended<br/>March 31,</b> |             |                         |
|-------------------------|---|-------------|-------------------------|
|                         | <b>2009</b>                             | <b>2008</b> | <b>Aggregate Change</b> |
|                         | <b>(in thousands)</b>                   |             |                         |
| <i>Interest expense</i> | \$ 53                                   | \$ 47       | \$ 6                    |

Interest expense results from our capital lease obligations associated with fixed asset acquisitions. The increase in interest expense for the three months ended March 31, 2009, as compared to the same period in 2008, was due to higher outstanding balances on capital lease obligations outstanding during the period.

**Income tax benefit**

|                           | <b>Three Months Ended<br/>March 31,</b> |             |                         |
|---------------------------|---|-------------|-------------------------|
|                           | <b>2009</b>                             | <b>2008</b> | <b>Aggregate Change</b> |
|                           | <b>(in thousands)</b>                   |             |                         |
| <i>Income tax benefit</i> | \$ 66                                   | \$          | \$ 66                   |

We recorded an income tax benefit of approximately \$66,000 for the period ended March 31, 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 March 31, 2009, we had approximately \$104.8 million in cash, cash equivalents and available-for-sale securities, as compared to approximately \$134.5 million as of December 31, 2008, a decrease of approximately \$29.7 million. The decrease was primarily attributable to the costs associated with our research and development activities. 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.

Table of Contents

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. 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 be able to 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:

- 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;
  
- our ability to establish new collaborations and the terms thereof;
  
- 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 would otherwise choose or may adversely affect our ability to operate as a going concern. For the three months ended March 31, 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.

Table of Contents**Cash Flows from Operating, Investing and Financing Activities**

|  | <b>Three Months Ended</b> |             |
|--|---------------------------|-------------|
|  | <b>March 31,</b>          |             |
|  | <b>2009</b>               | <b>2008</b> |
| Net cash provided by (used in):                      |                           |             |
| Net cash used in operating activities                | \$ (29,062)               | \$ (27,080) |
| Net cash provided by (used in) investing activities  | 20,124                    | (43,226)    |
| Net cash (used in) provided by financing activities  | (338)                     | 128,399     |
| Net (decrease) increase in cash and cash equivalents | \$ (9,276)                | \$ 58,093   |

Net cash used in operating activities was \$29.1 million for the three months ended March 31, 2009, compared to \$27.1 million for the three months ended March 31, 2008. The increase in net cash used in operating activities was primarily due to the increase in costs related to our two Phase 2b clinical trials (*TASKi2* and *TASKi3*), as well as the related extension trials in RA patients and manufacturing R788 material to be used in these clinical trials. 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 \$20.1 million for the three months ended March 31, 2009, compared to net cash used in investing activities of \$43.2 million for the three months ended March 31, 2008. Net cash provided by investing activities in 2009 was due to maturities of available-for-sale securities of \$44.2 million and sale of available-for-sale securities of \$3.0 million, partially offset by purchases of available-for-sale securities of \$27.0 million. Net cash used in investing activities for the three months ended March 31, 2008 related primarily to purchases of short-term investments, partially offset by maturities of short-term investments. Capital expenditures were \$11,000 in 2009 compared to \$297,000 in 2008.

Net cash used in financing activities was \$338,000 for the three months ended March 31, 2009, compared to net cash provided by financing activities of \$128.4 million for the same period in 2008. Net cash used in financing activities in first quarter of 2009 related mainly to payments of capital lease obligations of \$436,000, partially offset by proceeds from the exercise of outstanding options of \$98,000. In the first quarter of 2008, we completed a public offering in which we received net proceeds of approximately \$127.5 million. We also receive proceeds from the exercise of outstanding options of approximately \$1 million in the first quarter of 2008. Proceeds from capital lease financing were \$219,000 and payments for capital lease financing were \$316,000 in the first quarter of 2008.

**Off-Balance Sheet Arrangements**

As of March 31, 2009, we had no contractual arrangements that create potential material risks for us and are not recognized in our balance sheets.

**Contractual Obligations**

Income tax benefit



Edgar Filing: RIGEL PHARMACEUTICALS INC - Form 10-Q

As of March 31, 2009, we had the following contractual commitments (by fiscal year):

|                                      | <b>Total</b>      | <b>2009</b> | <b>2010 - 2011</b><br><b>(in thousands)</b> | <b>2012 - 2014</b> | <b>2015 - 2018</b> |
|--------------------------------------|-------------------|-------------|---|--------------------|--------------------|
| <b>Capital Lease obligations (1)</b> | \$ <b>3,182</b>   | \$ 1,013    | \$ 2,124                                    | \$ 45              | \$                 |
| <b>Facilities lease (2)</b>          | <b>134,876</b>    | 10,828      | 29,621                                      | 31,245             | 63,182             |
| <b>Total</b>                         | \$ <b>138,058</b> | \$ 11,841   | \$ 31,745                                   | \$ 31,290          | \$ 63,182          |

(1) As of March 31, 2009, we had approximately \$3.2 million in capital lease obligations (including the interest portion) associated with our equipment. All existing capital lease agreements as of March 31, 2009 are secured by the equipment financed, bear interest at rates between 4.99% and 10.85% and are due in monthly installments through 2012.

Table of Contents

(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 are obligated to repay the deferred 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. Accordingly, the timing and the aggregate amount of our rental obligations may change. The accompanying schedule reflects the outcome that we consider to be the most likely, which will result in the highest amount of rental obligations.

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

During the three months ended March 31, 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 period covered by this report, our disclosure controls and procedures were effective.

*Changes in Internal Controls.* There were no changes in our internal control over financial reporting that occurred during the period covered by this report 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**

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

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. 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 its costs and injunctive and/or equitable relief for purchasers of our common stock during the period between December 13, 2007 and October 27, 2008, including purchasers in the 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. It is possible that additional suits will be filed, or allegations received from stockholders, 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 cost will depend upon many unknown factors. The outcome of the litigation is necessarily uncertain, we could be forced to expend significant resources in the defense of this lawsuit and we may not prevail.

Table of Contents

**Item 1A. Risk Factors**

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

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 after the results of ongoing Phase 2b clinical trials of R788 are available, 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 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:

- 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;
  
- our ability to establish new collaborations and the terms thereof;
  
- the progress of research programs carried out by us;
  
- any changes in the breadth of our research and development programs;

Table of Contents

- 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.

**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 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 \$29.9 million for the three months ended March 31, 2009, \$132.3 million in 2008 and \$74.3 million in 2007. Currently, our revenues are generated solely from research milestone payments pursuant to our collaboration agreements and licenses and are insufficient to generate profitable operations. As of March 31, 2009, we had an accumulated deficit of approximately \$531.7 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 and T-cell lymphoma, which is proprietary to our company; one in safety testing and intended for psoriasis, which is proprietary to our company; one with six indications for oncology, which is subject to a collaboration agreement with Merck Serono; and one in safety testing and intended for allergic asthma, which is subject to a collaboration agreement with 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, regulatory compliance, manufacturing, competition and costs and expenses that may exceed current estimates. For example, in our recently completed Phase 2a clinical trial for R788 in RA, the most common clinically meaningful adverse events noted in the clinical trial included dose-related neutropenia, mild elevations of liver function tests and gastrointestinal side effects. 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 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.

Table of Contents

The results of preliminary studies do not necessarily predict clinical or commercial success, and larger later-stage clinical trials may fail to confirm the results observed in the preliminary studies. Our lead product candidate is in early development, having recently completed initial Phase 2 clinical trials in two indications. We are conducting additional Phase 2b trials, with larger numbers of patients, before proceeding into Phase 3 trials with R788 for RA. Furthermore, our Phase 2 clinical trial for ITP was conducted in highly refractory patients, as opposed to 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. 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.

**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 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 study, delays from scale up, 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.

Table of Contents

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 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.

**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 manufacturing capabilities or experience necessary to produce our product candidates, including R788. We rely on a single manufacturer for all of our clinical trials. We rely on manufacturers to produce and deliver all of the materials required for our preclinical and clinical 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, clinical trials and, if possible, to bring products to market in a timely manner.

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 Agency, and other 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 obtain approval from the FDA or 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.

Table of Contents

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. The 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 Johnson & Johnson, Novartis, Daiichi, 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. 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 stock.

Our business requires us to generate meaningful revenue from royalties and licensing agreements. To date, we have not received any revenue from royalties for the commercial sale of drugs, and we do not know when we will receive any such revenue, if at all. Likewise, 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 such or additional third parties 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 ongoing research and development efforts at Rigel, 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 corporate collaboration agreement with Daiichi ended in 2005. In 2004, we signed a new corporate collaboration with Merck, and the research phase of this collaboration ended in May 2007. In 2005, we signed additional collaborations with Pfizer and Merck Serono. 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 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.

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

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.

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

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

Table of Contents

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

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

Our success will depend to a large part on our own, our licensees' and our licensors' ability to obtain and defend patents for each party's respective technologies and the compounds and other products, if any, resulting from the application of such technologies. We have over 190 pending patent applications and over 130 issued patents in the United States that are owned or exclusively licensed in our field as well as 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 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, then our ability to receive patent protection or protect our proprietary information will 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.

Table of Contents

**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 also 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;
- 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 continue to reduce our workforce, 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;

Table of Contents

- 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 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, as well as other regulatory action against our potential products or us. Additionally, we have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approval.

If regulatory approval of a product is granted, this approval will be limited to those indications or disease states and conditions for which the product is demonstrated through clinical trials to be safe and efficacious. We cannot 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 associated with FDA approval described above and may also include additional risks.

**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

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

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.

Table of Contents

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.

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 potential drugs 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.

Table of Contents

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 are not currently aware of any specific causes for concern with respect to clinical liability claims. 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.

**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.

Table of Contents

**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. These, 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 and certain of our officers, directors and underwriters for our February 2008 stock offering. 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 alleges that we failed to disclose facts related to the response rates of trial patients in Mexico compared to trial patients in the U.S., an increase in average blood pressure of trial patients treated with R788 and an increase in liver enzymes in trial patients treated with R788 compared to those treated with placebo. The plaintiff seeks damages, including rescission or rescissory damages for purchasers in the stock offering, an award of its costs and injunctive and/or equitable relief for purchasers of our common stock during the period between December 13, 2007 and October 27, 2008, including purchasers in the 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. It is possible that additional suits will be filed, or allegations received from stockholders, 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 cost will depend upon many unknown factors. The outcome of the litigation is necessarily uncertain, 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 more 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 securities and those of other biotechnology companies have been highly volatile and may continue to be highly volatile in the future. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

- the progress and success of clinical trials and preclinical activities (i.e., studies, 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;

Table of Contents

- 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.

**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:

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

- 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 2. Unregistered Sales of Equity Securities and Use of Proceeds**

In connection with an amendment to our build-to-suit lease agreement in order to defer certain repayment of rental obligations, we cancelled an existing warrant granting HCP Estates USA Inc., an affiliate of our landlord, the right to purchase 100,000 shares of common stock and issued a new warrant granting HCP BTC, LLC, our landlord, the right to purchase 200,000 shares of common stock at an exercise price per share of \$6.61. The new warrant remains exercisable until March 2016. The warrant was issued in reliance on the exemptions from registration under Regulation D of the Securities Act of 1933, as amended. We relied on our landlord's representations and covenants in support of the satisfaction of the conditions contained in Regulation D. See Note 10 (Amendment to the Build-to-Suit Lease Agreement) to the Financial Statements above for a discussion of the warrant.

Table of Contents

**Item 6. Exhibits**

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

| <b>Exhibit<br/>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.  |
| 10.1                      | Amendment No. Four to the Build-to-Suit Lease between Rigel and HCP BTC, LLC dated February 1, 2009.  |
| 10.24                     | 2009 Cash Incentive Plan. (5)   |
| 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) dated June 24, 2003, and incorporated herein by reference.
  - (5) Filed as an exhibit to Rigel's Current Report on Form 8-K (No. 000-29889) dated March 30, 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: May 5, 2009

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

Date: May 5, 2009







**Table of Contents**





**INDEX TO EXHIBITS**

Edgar Filing: RIGEL PHARMACEUTICALS INC - Form 10-Q

| <b>Exhibit<br/>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.  |
| 10.1                      | Amendment No. Four to the Build-to-Suit Lease between Rigel and HCP BTC, LLC dated February 1, 2009.  |
| 10.24                     | 2009 Cash Incentive Plan. (5)   |
| 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.
  - (3) 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) dated June 24, 2003, and incorporated herein by reference.
  - (5) Filed as an exhibit to Rigel's Current Report on Form 8-K (No. 000-29889) dated March 30, 2009, and incorporated herein by reference.