

LUNA INNOVATIONS INC
Form 10-Q
November 13, 2007
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2007

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 000-52008

LUNA INNOVATIONS INCORPORATED

(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction of Incorporation or Organization)

1 Riverside Circle, Suite 400

Roanoke, VA 24016

(Address of Principal Executive Offices)

54-1560050
(I.R.S. Employer Identification Number)

Edgar Filing: LUNA INNOVATIONS INC - Form 10-Q

(540) 769-8400

(Registrant's Telephone Number, Including Area Code)

1703 South Jefferson Street

Roanoke, VA 24016

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

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 is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large Accelerated Filer Accelerated Filer Non-Accelerated Filer

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: As of November 1, 2007, there were 10,373,088 shares of the registrant's common stock outstanding.

Table of Contents

LUNA INNOVATIONS INCORPORATED
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED SEPTEMBER 30, 2007
TABLE OF CONTENTS

<u>PART I. FINANCIAL INFORMATION</u>	3
ITEM 1. <u>FINANCIAL STATEMENTS</u>	3
ITEM 2. <u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	11
ITEM 3. <u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	17
ITEM 4. <u>CONTROLS AND PROCEDURES</u>	17
<u>PART II. OTHER INFORMATION</u>	17
ITEM 1. <u>LEGAL PROCEEDINGS</u>	17
ITEM 1A. <u>RISK FACTORS</u>	18
ITEM 2. <u>UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS</u>	33
ITEM 3. <u>DEFAULTS UPON SENIOR SECURITIES</u>	33
ITEM 4. <u>SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS</u>	33
ITEM 5. <u>OTHER INFORMATION</u>	33
ITEM 6. <u>EXHIBITS</u>	33
<u>SIGNATURES</u>	34
<u>EXHIBIT INDEX</u>	35

Table of Contents**PART I. FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****Luna Innovations Incorporated****Consolidated Balance Sheets**

	September 30, 2007 (unaudited)	December 31, 2006
Assets		
Current assets		
Cash and cash equivalents	\$ 12,528,394	\$ 17,866,753
Accounts receivable, net	8,779,631	7,233,406
Refundable income taxes	396,062	396,062
Inventory	1,551,020	843,294
Other current assets	375,958	503,703
Total current assets	23,631,065	26,843,218
Property and equipment, net	6,029,655	5,730,094
Intangible assets, net	1,961,815	2,031,489
Deferred tax asset	600,000	600,000
Other assets	11,304	12,413
Total assets	\$ 32,233,839	\$ 35,217,214
Liabilities and stockholders' equity		
Current liabilities		
Current portion of capital lease obligation	\$ 42,797	\$ 85,378
Current portion of long-term debt obligation		214,955
Accounts payable	2,681,763	2,757,381
Accrued liabilities	4,774,346	3,627,277
Deferred credits	1,750,551	874,676
Total current liabilities	9,249,457	7,559,667
Long-term capital lease obligation	7,418	27,873
Long-term debt obligation	5,000,000	5,000,000
Deferred credits	604,418	554,418
Total liabilities	14,861,293	13,141,958
Stockholders' equity:		
Common stock, par value \$0.001, 100,000,000 shares authorized, 10,342,565 and 9,911,546 shares issued and outstanding	10,342	9,912
Additional paid-in capital	33,580,843	31,585,762
Accumulated deficit	(16,218,639)	(9,520,418)
Total stockholders' equity	17,372,546	22,075,256

Total liabilities and stockholders equity	\$ 32,233,839	\$ 35,217,214
--	----------------------	----------------------

The accompanying notes are an integral part of these consolidated financial statements.

Table of Contents**Luna Innovations Incorporated****Consolidated Statements of Operations**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007 (unaudited)	2006 (unaudited)	2007 (unaudited)	2006 (unaudited)
Revenues:				
Technology development revenues	\$ 5,952,747	\$ 4,885,854	\$ 17,091,452	\$ 12,977,066
Product and license revenues	2,867,453	1,163,663	6,654,200	2,521,403
Total revenues	8,820,200	6,049,517	23,745,652	15,498,469
Cost of revenues:				
Technology development costs	4,008,829	3,587,280	11,929,264	9,600,404
Product and license costs	1,281,367	520,699	2,670,916	1,194,969
Total cost of revenues	5,290,196	4,107,979	14,600,180	10,795,373
Gross Profit	3,530,004	1,941,538	9,145,472	4,703,096
Operating expense	5,511,561	4,110,926	16,182,168	11,805,277
Operating loss	(1,981,557)	(2,169,388)	(7,036,696)	(7,102,181)
Other income				
Other income	49,515	934	47,904	10,331
Interest income, net	93,690	232,649	290,571	345,794
Total other income	143,205	233,583	338,475	356,125
Loss before income taxes	(1,838,352)	(1,935,805)	(6,698,221)	(6,746,056)
Income tax expense		12,829		12,829
Net loss	\$ (1,838,352)	\$ (1,948,634)	\$ (6,698,221)	\$ (6,758,885)
Net loss per share:				
Basic	\$ (0.18)	\$ (0.20)	\$ (0.66)	\$ (0.87)
Diluted	\$ (0.18)	\$ (0.20)	\$ (0.66)	\$ (0.87)
Weighted average shares:				
Basic	10,293,557	9,842,265	10,134,313	7,743,885
Diluted	10,293,557	9,842,265	10,134,313	7,743,885

The accompanying notes are an integral part of these consolidated financial statements.

Table of Contents

Luna Innovations Incorporated
Consolidated Statements of Cash Flows

	Nine months ended September 30,	
	2007	2006
	(unaudited)	
Cash flows used in operating activities		
Net loss	\$ (6,698,221)	\$ (6,758,885)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,324,155	792,725
Share-based compensation	1,722,734	1,164,709
Change in assets and liabilities:		
Accounts receivable	(1,546,225)	(64,536)
Refundable income taxes		118,735
Inventory	(707,726)	
Other current assets	128,854	(524,201)
Accounts payable and accrued expenses	1,071,451	(545,211)
Deferred credits	925,875	(477,426)
Net cash used in operating activities	(3,779,103)	(6,294,090)
Cash flows used in investing activities		
Acquisition of property and equipment	(1,233,932)	(1,377,466)
Intangible property costs	(320,110)	(282,840)
Net cash used in investing activities	(1,554,042)	(1,660,306)
Cash flows from financing activities		
Payments on capital lease obligations	(63,036)	(74,229)
Proceeds from the issuance of common stock, net		17,866,241
Proceeds from the exercise of options and warrants	272,777	89,561
Payment of debt	(214,955)	
Net cash (used in) provided by financing activities	(5,214)	17,881,573
Net change in cash	(5,338,359)	9,927,177
Cash and cash equivalents beginning of period	17,866,753	12,514,839
Cash and cash equivalents end of period	\$ 12,528,394	\$ 22,442,016

The accompanying notes are an integral part of these consolidated financial statements.

Table of Contents

Luna Innovations Incorporated

Notes to Consolidated Financial Statements

1. Basis of Presentation and Significant Accounting Policies

Nature of Operations

Luna Innovations Incorporated (Luna Innovations) was incorporated in the Commonwealth of Virginia in 1990 and subsequently reincorporated in the State of Delaware in April 2003. We research, develop and commercialize innovative technologies in two primary areas of focus: instrumentation and test & measurement products and healthcare products. We have a disciplined and integrated business model that is designed to accelerate the process of bringing new and innovative products to market. We identify technologies that can fulfill unmet market needs and then take these technologies from the applied research stage through commercialization.

Unaudited Interim Financial Information

The accompanying unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (US GAAP) and with the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities Exchange Act of 1934. Accordingly, they do not include all of the information and footnotes required by US GAAP for audited financial statements. The unaudited consolidated financial statements have been prepared on the same basis as the annual financial statements and in the opinion of management reflect all adjustments, consisting of only normal recurring accruals, considered necessary to present fairly our financial position at September 30, 2007 and results of operations and cash flows for the three and nine months ended September 30, 2007 and 2006. The results of operations for the three and nine months ended September 30, 2007 are not necessarily indicative of the results that may be expected for the year ending December 31, 2007.

The consolidated financial statements, including the Company's significant accounting policies, should be read in conjunction with the audited Consolidated Financial Statements and the notes thereto included in the Company's Annual Report on Form 10-K as amended and filed with the Securities and Exchange Commission on March 30, 2007. As used herein, the terms Luna , Company , we , our and us mean Luna Innovations Incorporated and its consolidated subsidiaries.

Consolidation Policy

Our consolidated financial statements are prepared in accordance with US GAAP and include the accounts of the Company, its wholly owned subsidiaries and other entities in which the Company has a controlling financial interest. We eliminate from our financial results all significant intercompany transactions. The Company does not have any investments in entities it believes are variable interest entities for which the Company is the primary beneficiary.

Use of Estimates

The preparation of our consolidated financial statements in accordance with US GAAP requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements and accompanying notes. Although these estimates and assumptions are based on our knowledge of current events and actions we may undertake in the future, actual results may differ.

Inventory

Inventory consists of finished goods and parts valued at the lower of cost (determined on the first-in, first-out basis) or market. We provide reserves for estimated obsolescence or unmarketable inventory equal to the difference between the cost of the inventory and the estimated market value based upon assumptions about future demand and market conditions.

The following table presents the components of inventory for the nine months ending:

Edgar Filing: LUNA INNOVATIONS INC - Form 10-Q

	September 30, 2007	December 31, 2006
Raw Materials	\$ 1,202,259	\$ 585,813
Work in process	\$ 203,943	\$ 126,597
Finished Goods	\$ 144,818	\$ 130,885
Total Inventory	\$ 1,551,020	\$ 843,294

Table of Contents**Net Loss Per Share**

We compute net loss per share in accordance with Statement of Financial Accounting Standards (SFAS) No. 128, *Earnings Per Share*. Basic per share data is computed by dividing loss available to common shareholders by the weighted average number of shares outstanding during the period. Diluted per share data is computed by dividing loss available to common shareholders by the weighted average shares outstanding during the period increased to include, if dilutive, the number of additional common share equivalents that would have been outstanding if potential common shares had been issued using the treasury stock method. Diluted per share data would also include the potential common share equivalents relating to convertible securities by application of the if-converted method.

The following table presents basic and diluted net loss per share:

	Nine Months Ended			
	Three Months Ended		September 30,	
	September 30,		September 30,	
	2007	2006	2007	2006
Net loss	\$ (1,838,352)	\$ (1,948,634)	\$ (6,698,221)	\$ (6,758,885)
Weighted average shares basic	10,293,557	9,842,265	10,134,313	7,743,885
Dilutive effect of common stock equivalents: Shares issued upon the exercise of stock options and warrants				
Weighted averages shares diluted	10,293,557	9,842,265	10,134,313	7,743,885
Net loss per share basic	\$ (0.18)	\$ (0.20)	\$ (0.66)	\$ (0.87)
Net loss per share diluted	\$ (0.18)	\$ (0.20)	\$ (0.66)	\$ (0.87)

The effect of 3,401,598 and 3,800,510 common stock equivalents are ignored for the three months ended September 30, 2007 and 2006, respectively, as they are antidilutive to earnings per share. The effect of 3,351,533 and 3,842,338 common stock equivalents are ignored for the nine months ended September 30, 2007 and 2006, respectively, as they are antidilutive to earnings per share. In addition, the conversion of the \$5.0 million in senior convertible promissory notes would have been antidilutive for all such periods.

Share Based Compensation

We have a stock-based compensation plan, which is described further in Note 9 to the Financial Statements in the Company's Annual Report on Form 10-K as amended and filed with the Securities and Exchange Commission on March 30, 2007. Effective January 1, 2006, we adopted SFAS No. 123R, *Share-Based Payment* (SFAS No. 123R) using the modified prospective transition method. Under this transition method, our financial statements for the periods prior to January 1, 2006 have not been restated. However, new awards and awards modified, repurchased or cancelled after January 1, 2006, result in compensation expense based on the fair value of the stock option as determined by the Black-Scholes option pricing model. We amortize share-based compensation for such awards on a straight-line basis over the related service period of the awards taking into account the effects of the employees' expected exercise and post-vesting employment termination behavior.

We account for share-based employee compensation arrangements in accordance with the provisions of SFAS No. 123R. We account for equity instruments issued to non-employees in accordance with the provisions of SFAS No. 123R and Emerging Issues Task Force (EITF) Issue No. 96-18.

The fair value of each option granted is estimated as of the grant date using the Black-Scholes option pricing model with the following assumptions:

	Nine Months Ended	Nine Months Ended
	September 30, 2007	September 30, 2006
Risk-free interest rate range	4.5% - 5.2%	4.55% - 5.20%

Edgar Filing: LUNA INNOVATIONS INC - Form 10-Q

Expected life of option range of years	7.0 - 7.5	7.0 - 7.5
Expected stock price volatility	56.8% - 64%	64%
Expected dividend yield		

The risk-free interest rate is based on US Treasury interest rates, the terms of which are consistent with the expected life of the stock options. Expected volatility for the nine months ended September 30, 2007 was based on the average volatility of comparable public companies due to the lack of historical market price data for our stock on such date. The expected life and estimated post employment termination behavior is based upon historical experience of homogeneous groups within our company.

Table of Contents

A summary of the status of our 2003 Stock Plan and 2006 Equity Incentive Plan is presented below for the periods indicated:

	Number of Shares	Options Outstanding Price per Share			Aggregate Intrinsic Value (1)	Options Exercisable		
		Range	Weighted Average	Number of Shares		Weighted Average Exercise Price	Aggregate Intrinsic Value (1)	
Balance, December 31, 2006	4,982,594	\$0.35 - \$7.08	\$ 1.26	\$ 12,215,503	2,322,665	\$ 2.99	\$ 1,961,849	
Granted	379,000	\$3.67 - \$3.69	\$ 3.69					
Exercised	(107,591)	\$0.35 - \$1.77	\$ 0.43					
Canceled	(38,288)	\$0.35 - \$6.00	\$ 4.00					
Balance, March 31, 2007	5,215,715	\$0.35 - \$7.08	\$ 1.43	\$ 10,978,075	2,638,065	\$ 0.75	\$ 6,987,607	
Granted	228,650	\$3.16 - \$4.72	\$ 3.84					
Exercised	(211,950)	\$0.35 - \$1.77	\$ 0.94					
Canceled	(139,097)	\$0.35 - \$6.00	\$ 1.52					
Balance, June 30, 2007	5,093,318	\$0.35 - \$7.08	\$ 1.56	\$ 14,724,876	2,652,454	\$ 0.81	\$ 9,473,547	
Granted	85,250	\$4.15 - \$4.15	\$ 4.15					
Exercised	(80,640)	\$0.35 - \$1.77	\$ 0.36					
Canceled	(184,756)	\$0.35 - \$6.00	\$ 2.07					
Balance, September 30, 2007	4,913,172	\$0.35 - \$7.08	\$ 1.60	\$ 13,806,389	2,798,887	\$ 0.92	\$ 9,632,970	

(1) The intrinsic value of an option represents the amount by which the market value of the stock exceeds the exercise price of the option of in-the-money options only. The aggregate intrinsic value is based on the price of \$4.33 on September 30, 2007, which represents the closing price of the Company's Common Stock on the NASDAQ Global Market on September 28, 2007, the last trading day prior to September 30, 2007.

At September 30, 2007, our 4,913,172 million outstanding stock options had a weighted average remaining contractual term of 7.8 years, and our 2,798,887 million outstanding and exercisable stock options had a weighted average remaining contractual term of 7.3 years.

For the three and nine months ended September 30, 2007, we recognized \$626,179 and \$1,722,734, respectively, in share-based payment expense. We will recognize approximately \$6.5 million over the remaining requisite service period of approximately four years.

Income Taxes

Our effective quarterly tax rate is estimated based upon the effective tax to be applicable to the full fiscal year. A deferred tax asset of \$600,000 was recorded at both December 31, 2006 and September 30, 2007, based upon management's assessment that more likely than not the benefit will be realized in future periods.

Effective January 1, 2007, we adopted FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* (FIN 48). FIN 48 prescribes a more-likely-than-not threshold of financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. This interpretation also provides guidance on derecognition of income tax assets and liabilities, classification of current and deferred tax assets and liabilities, accounting for interest and penalties associated with tax positions, accounting for income taxes in interim periods and income tax disclosures. The cumulative effects of applying this interpretation did not have a significant impact on either our net deferred tax assets or valuation allowance.

We have made no adjustments to the classification of assets or liabilities, or recognition of any income tax related expenses, in connection with the adoption of FIN 48.

Recent Accounting Pronouncements

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*. SFAS No. 157 clarifies the principle that fair value should be based on the assumptions market participants would use when pricing an asset or liability and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. SFAS No. 157 is effective for the fiscal year beginning January 1, 2007. The Company's adoption of SFAS No. 157 did not have a material impact on its consolidated financial statements.

Table of Contents

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities (as amended)*. SFAS No. 159 permits entities to choose to measure eligible items at fair value at specified election dates, and requires entities to report unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting date. SFAS No. 159 is effective for the first quarter of the year beginning January 1, 2008. The Company's adoption of SFAS No. 159 will not have a material impact on its consolidated financial statements.

1. Reclassifications

Certain amounts in prior quarters have been reclassified to conform to current period presentation.

2. Line of Credit

At the end of June 2007, the Company entered into a new line of credit agreement with First National Bank (FNB) for a 364 day term. The new line of credit increased the amount available to borrow from \$2.5 million to \$3.0 million. There were no outstanding balances on our line of credit with First National Bank (FNB) at September 30, 2007 and at December 31, 2006, and no borrowings during the nine month period ended September 30, 2007. The agreement also includes a \$1.0 million sub-limit under the line of credit for the issuance of letters of credit. FNB issued a \$719,500 letter of credit on our behalf to the Industrial Development Authority of Montgomery County, Virginia, in conjunction with the Company's execution of an office lease. As of October 1, 2007, the balance of the letter of credit was reduced to \$599,583 in connection with a reduction in scheduled future rent payments due.

3. Initial Public Offering and Capital Structure

In June, 2006, we sold 3,500,000 shares of common stock in our initial public offering at \$6.00 per share resulting in gross proceeds of \$21.0 million. In connection with this offering, we paid \$1.47 million in underwriting discounts and commissions and incurred other offering expenses of approximately \$1.66 million. The net proceeds from the offering were approximately \$17.9 million.

Concurrent with the initial public offering, all outstanding shares of our Class A voting Common Stock, Class B non-voting Common Stock, and Class C voting Common Stock were converted to shares of common stock on a one-for-one basis. All outstanding shares of our Redeemable Class B Common Stock converted to common stock on a one-for-one basis as the successful initial public offering eliminated the redeemable feature of such shares. We also issued 96,724 shares of common stock to Carilion Clinic in accordance with the anti-dilution provisions of our previous amended and restated certificate of incorporation, which was adopted in connection with our Class C Common Stock financing in December 2005. Upon the closing of our initial public offering the total authorized shares of our capital stock increased to 100,000,000 shares of common stock and 5,000,000 shares of preferred stock.

For the nine months ended September 30, 2007, our capital structure changed as follows:

	Common Stock		Additional Paid-in Capital
	Shares	\$	
Balances, December 31, 2006	9,911,546	\$ 9,912	\$ 31,585,762
Exercise of stock options	107,591	107	46,206
Share-based compensation			522,389
Balances, March 31, 2007	10,022,254	\$ 10,022	\$ 32,154,357
Exercise of stock options	211,950	212	197,649
Share-based compensation			574,166
Warrants exercised and stock issued	11,294	11	11
Balances, June 30, 2007	10,250,208	10,250	32,926,183
Exercise of stock options	80,640	81	28,468
Share-based compensation			626,179
Warrants exercised and stock issued	11,717	11	13

Edgar Filing: LUNA INNOVATIONS INC - Form 10-Q

Balances, September 30, 2007

10,342,565

10,342

33,580,843

Table of Contents**4. Operating Segments**

Our operations are divided into two operating segments Technology Development and Product and Licensing.

The Technology Development segment provides applied research to customers in our areas of focus. Our engineers and scientists collaborate with our network of government, academic and industry experts to identify technologies and ideas with promising market potential. We then compete to win fee-for-service contracts from government agencies and industrial customers who seek innovative solutions to practical problems that require new technology. The Technology Development segment derives its revenue primarily from services.

The Product and Licensing segment develops and sells products or licenses technologies based on commercially viable concepts developed, in whole or in part, by the Technology Development segment. The Product and Licensing segment derives its revenue from product sales, product development fees and technology licenses.

The Chief Executive Officer and his direct reports collectively represent our chief operating decision makers, and they evaluate segment performance based primarily on revenue and operating income or loss. The accounting policies of our segments are the same as those described in the summary of significant accounting policies (see Note 1 to our Financial Statements, Organization and Summary of Significant Accounting Policies, presented in the Company's Annual Report on Form 10-K as amended and filed with the Securities and Exchange Commission on March 30, 2007).

The table below presents revenues and operating loss for reportable segments:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Technology Development Revenue	\$ 5,952,747	\$ 4,885,854	\$ 17,091,453	\$ 12,977,066
Product and License Revenue	2,867,453	1,163,663	6,654,200	2,521,403
Total Revenue	\$ 8,820,200	\$ 6,049,517	\$ 23,745,653	\$ 15,498,469
Technology Development Operating Loss	\$ (1,164,837)	\$ (715,563)	\$ (3,150,601)	\$ (2,626,963)
Product and License Operating Loss	(816,720)	(1,453,825)	(3,886,095)	(4,472,218)
Total Operating Loss	\$ (1,981,557)	\$ (2,169,388)	\$ (7,036,696)	\$ (7,102,181)

Additional segment information is as follows:

	September 30,	December 31,
	2007	2006
Total segment assets:		
Technology Development	\$ 28,251,662	\$ 29,108,744
Product and License	3,982,177	6,108,470
Total	\$ 32,233,839	\$ 35,217,214

There are no material inter-segment revenues for any period presented.

The United States Government accounted for approximately 72% of total consolidated revenues for the three months ended September 30, 2007 and 2006, and 77% and 74% of revenues for the nine months ended September 30, 2007 and September 30, 2006, respectively.

Edgar Filing: LUNA INNOVATIONS INC - Form 10-Q

International revenues (customers outside of the United States) accounted for 0.7% and 4.0% of total revenues for the three months ended September 30, 2007 and 2006, and 0.7% and 3.5% of total revenues for the nine months ended September 30, 2007 and September 30, 2006.

5. Contingencies and Guarantees

The Company is from time to time involved in certain legal proceedings in the ordinary course of conducting its business. While the ultimate liability pursuant to these actions cannot currently be determined, the Company believes these legal proceedings will not have a material adverse effect on its financial position or results of operations.

On June 22, 2007, Hansen Medical, Inc. (Hansen) filed a lawsuit against us in California State Court, Santa Clara County, alleging

Table of Contents

misappropriation of trade secrets, unfair competition, breach of contract, and breach of the implied covenant of good faith and fair dealing. The claims allegedly stem from our past relationship with Hansen and our past and future relationship with Intuitive Surgical, Inc. (Intuitive). The lawsuit makes an unspecified claim for damages, however Hansen has not indicated how it will substantiate such damages and we are unable to reasonably estimate the amount of damages, if any, that Hansen will seek. Additionally, on October 12, 2007, the Company filed a cross-claim against Hansen alleging misappropriation of trade secrets, unfair competition, breach of contract, and breach of the implied covenant of good faith and fair dealing and seeking a declaratory judgment as to the parties' rights and obligation. The Company's cross-claim seeks damages and equitable relief. We cannot predict the ultimate outcome of this litigation and we are unable to estimate any potential liability we may incur.

The Company has an outstanding letter of credit at September 30, 2007 of \$719,500 to the Industrial Development Authority of Montgomery County, Virginia to support a lease of office space. This letter of credit expires in 2011.

The Company has an agreement with two suppliers to purchase inventory and estimates its noncancellable obligation to approximate \$1.3 million through December 2008.

The Company has entered into indemnification agreements with its officers and directors, to the extent permitted by law, pursuant to which the Company has agreed to reimburse the officers and directors for legal expenses in the event of litigation and regulatory matters. The terms of these indemnification agreements provide for no limitation to the maximum potential future payments. The Company has a directors and officers insurance policy that may, in certain instances, mitigate the potential liability and payments.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the related notes to those statements included elsewhere in this report. In addition to historical financial information, the following discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 that involve risks, uncertainties and assumptions. These statements include, among other things, statements concerning:

our expectations regarding the relative growth of our product sales and licensing revenue and our margins;

our expectation that future product and licensing revenue will reflect a broader and more diversified mix of products;

our expectation that technology development revenue will continue to represent a significant portion of our total revenue for the foreseeable future;

our expectations regarding investments in product development and commercialization, and our expectation that such investments will lead to increased product revenue;

our expectation that we will continue to incur significant expenses associated with being a public company and will likely continue to incur increased operating expenses and substantial losses;

our expectations that operating revenue will rise at a lesser rate of growth as we continue to invest in new product development and product sales;

our expectation that our product revenue will increase in the near term; and

Edgar Filing: LUNA INNOVATIONS INC - Form 10-Q

our expectation that we will not need to draw down our line of credit facility.

Our actual results and timing of selected events may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those discussed under Risk factors and elsewhere in this report, as well as those discussed in other documents we file with the Securities and Exchange Commission. We take no obligation to revise or otherwise disclose any revision to these forward-looking statements.

Overview

We research, develop and commercialize innovative technologies in two primary areas of focus: instrumentation and test & measurement products and healthcare products. We have a disciplined and integrated business model that is designed to accelerate the process of bringing new and innovative products to market. We identify technologies that can fulfill unmet market needs and then take these technologies from the applied research stage through commercialization.

Table of Contents

To manage a diverse set of products effectively across a range of development stages, we are organized into two main groups: our Technology Development Division (which generates contract research revenue) and our Products Division (which generates product and licensing revenue). Although revenues from product sales and licensing currently represent less than half of our total revenues, we continue to invest in product development and commercialization, which we anticipate will lead to increased product sales and improved margins. In the future, while we anticipate continued growth in technology development revenue, we expect that revenues from product sales and licensing will represent a larger proportion of our total revenues. In addition, we anticipate that future product and licensing revenues will reflect a broader and more diversified mix of products.

Our revenues were \$23.7 million and \$15.4 million during the nine months ended September 30, 2007 and 2006, respectively, and we had net losses of \$6.7 million and \$6.8 million for the same periods, respectively. We generate revenues through technology development services provided under contractual arrangements, product sales and license fees. Historically, our technology development revenues, which consist primarily of government-funded research, have accounted for a large and growing proportion of our total revenues, and we expect that they will continue to represent a significant portion of our total revenues for the foreseeable future. Our technology development revenues grew from \$13.0 million to \$17.1 million for the nine months ended September 30, 2006 and 2007, respectively. We regularly have a backlog of contracts for which work has been scheduled, but for which a specified portion of work has not yet been completed. We define backlog as the dollar amount of obligations payable to us under negotiated contracts upon completion of a specified portion of work that has not yet been completed, exclusive of revenues previously recognized for work already performed under these contracts, if any. The approximate value of our backlog was \$29.5 million as of September 30, 2007.

Revenues from product sales currently represent a smaller proportion of our total revenues, and, historically, we have derived most of these revenues from the sales of our instrumentation and test and measurement products, including products that make use of light-transmitting optical fibers, or fiber optics. License revenues associated with our proprietary technologies have been significant in prior years. Although we have been successful in licensing certain technology, we do not currently earn significant license revenues. However, over time we do intend to gradually increase such revenues. In the near term, we expect revenues from product sales to increase because of growth in our existing instrumentation and test and measurement products and because of growth in new product lines, particularly medical device products. We also expect to increase our investments in product development and commercialization, which we anticipate will lead to increased product sales growth. In the future, we expect that revenues from product sales will represent a larger proportion of our total revenues and that as we develop and commercialize new products, these revenues will reflect a broader and more diversified mix of products.

In connection with becoming a public company, we have incurred and will continue to incur significant additional expenses such as audit fees, professional fees, increased directors and officers insurance, advisory board and board of directors compensation, and expenses related to hiring additional personnel and expanding our administrative functions. Many of these expenses were not incurred by us in periods prior to our initial public offering. In addition, upon receiving the net proceeds from our initial public offering, we implemented a strategy for expansion that has significantly increased our operating expenses and will likely continue to result in substantial losses. We incurred consolidated net losses of approximately \$6.7 million and \$6.8 million for the nine month periods ended September 30, 2007 and 2006, respectively. We expect to continue to incur significant additional expenses as we expand our business, including increased expenses for research and development, sales and marketing, manufacturing, finance and accounting personnel and expenses associated with being a public company. We may also grow our business in part through acquisitions of additional companies and complementary technologies which could cause us to incur greater than anticipated transaction expenses, amortization or write-offs of intangible assets and other acquisition-related expenses. As a result, we expect that we will continue to incur losses in 2007 and that these losses could be substantial. We believe that our current cash on hand and cash available under our line of credit agreement will be sufficient to fund operations for the next 12 months.

As a result of the adoption of the provisions of the Financial Accounting Standards Board's revised Statement of Financial Accounting Standards No. 123 *Share-Based Payment* (SFAS No. 123R), our operating expenses for 2006 and to date for fiscal year 2007 include stock-based compensation charges. We recorded stock-based compensation charges of \$0.6 million for the three months ended September 30, 2007. We also expect to record an aggregate stock-based compensation charge for stock options granted through September 30, 2007 of \$6.5 million to be recognized over years 2007 through 2011.

Description of Our Revenues, Costs and Expenses

Revenues

We generate revenues from technology development (contract research), contract product development, and product sales. We derive technology development revenues from providing research and development services to third parties, including government entities, academic institutions and corporations, and from achieving milestones established by some of

Table of Contents

these contracts and in collaboration agreements. In general, we complete contracted research over periods ranging from six months to three years, and recognize these revenues over the life of the contract as costs are incurred or upon the achievement of certain milestones built into the contracts. Our product revenues reflect amounts that we receive from sales of our products or development of products for third parties and currently represent approximately 28% of our total revenues.

Cost of Revenues

Cost of revenues associated with technology development revenues consists of costs associated with performing the related research activities, including direct labor, amounts paid to subcontractors and overhead allocated to technology development activities.

Cost of revenues associated with product sales and license revenues consists of license fees for use of certain technologies; product manufacturing costs including all direct material and direct labor costs; amounts paid to our contract manufacturers; manufacturing, shipping and handling; provisions for product warranty; and inventory obsolescence, as well as overhead allocated to these activities.

Operating Expense

Operating expense consists of selling, general and administrative expenses, as well as expenses related to research and development, depreciation of fixed assets and amortization of intangible assets. These expenses also include: compensation for employees in executive and operational functions including certain non-cash charges related to expenses from option grants; facilities costs; professional fees; salaries, commissions, travel expense and related benefits of personnel engaged in sales, product management and marketing activities; costs of marketing programs and promotional materials; salaries, bonuses and related benefits of personnel engaged in our own research and development beyond the scope and activities of our Technology Development Division; product development activities not provided under contracts with third parties; and overhead costs related to these activities.

Interest Income/Expense

Interest expense historically related primarily to interest we paid under our senior secured revolving credit facility. As of September 30, 2007, there was no amount outstanding on our credit facility. Interest expense includes interest accrued on the outstanding aggregate principal of the senior convertible promissory notes issued to Carilion Clinic on December 30, 2005.

Interest income includes amounts earned on our cash deposits with financial institutions. During 2006 and the first three quarters of 2007, we invested the proceeds of the Carilion financing transactions and the net proceeds from our initial public offering in a money market account and draws from that account as needed to fund ongoing operations.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States (US GAAP). The preparation of these financial statements requires us to make estimates, assumptions and judgments that affect the amounts reported in our financial statements and the 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 may differ from these estimates under different assumptions or judgments. Our significant accounting policies are described in the Management Discussion and Analysis section and the notes to our audited consolidated financial statements previously included in our Annual Report on Form 10-K for the period ended December 31, 2006, as filed with the Securities and Exchange Commission on March 30, 2007.

Results of Operations

Three Months Ended September 30, 2007 Compared to Three Months Ended September 30, 2006

Revenues

Total revenues increased 46% to \$8.8 million for the three months ended September 30, 2007, from \$6.0 million for the three months ended September 30, 2006. The increase was due in part to increased product sales related to our Luna Technologies Division. Our acquisition of Luna Technologies in September 2005 and the subsequent product sales by that division are key elements of our strategic transition towards our goal of increased product sales revenues. We generated approximately \$2.9 million in product sales in the third quarter of 2007 as compared with

\$1.2 million in the third quarter of 2006.

Table of Contents

Growth in our technology development revenues also contributed to our overall growth in revenues for the third quarter of 2007 as compared with the third quarter of 2006. Technology development revenues increased 22% to \$5.9 million for the three months ended September 30, 2007 from \$4.8 million for the corresponding 2006 period. This increase was primarily a result of a continued strong success in obtaining research contracts, an increase in the size of certain awards, and the addition of direct contract personnel.

Cost of Revenues

Cost of revenues increased 29% to \$5.3 million for the three months ended September 30, 2007 from \$4.1 million for the corresponding 2006 period. The main component of this overall increase was increased costs of labor and materials related to increases in technology development revenue. New technology development cost of sales increases accounted for approximately \$0.4 million, or 36%, and product sales cost increases accounted for approximately \$0.8 million, or 64%, respectively, of the overall increase in costs of revenues.

Technology development costs increased 12% to \$4.0 million for the three months ended September 30, 2007 from \$3.6 million in the same period in 2006. This increase was consistent with the 22% increase in our technology development revenues, and was comprised primarily of additional direct labor and the technology associated overhead related to research and development activities.

Our overall gross margin improved as compared with the third quarter of 2006. Our overall gross margin during the three months ended September 30, 2007 was 40% compared to 32% during the same period in 2006. During the three months ended September 30, 2007, technology development activity returned a gross margin of approximately 33% compared to 27% in the same period of 2006. Product and license activity returned a gross margin of 55% for the three months ended September 30, 2007, compared to 55% for the same period in 2006. One of our objectives in seeking greater relative product sales is based on the goal of achieving higher margins to improve our overall profitability.

Operating Expense

Operating expense increased 35% to \$5.5 million for the three months ended September 30, 2007 from \$4.1 million for the corresponding quarter in 2006. Much of the increase in the second quarter of 2007 as compared to the same period in 2006 was due to indirect expenses in connection with implementing our business plan relating to commercializing new products and increasing our product sales capabilities. Consistent with our strategy of building a growing portfolio of businesses and products, we were and are actively hiring additional staff with related recruitment and relocation charges, incurring legal and professional fees and implementing various internal changes to prepare and to strengthen our existing infrastructure and management resources as a result of becoming a public company. With the completion of our second round financing with Carilion Clinic in December 2005, and the proceeds from our IPO in June 2006, we gained the necessary resources to begin implementing many of these important changes to our business. We expect that our operating expenses will remain at these increased levels in the coming months due to our continued growth and development and compliance with the various regulatory requirements associated with being a public company. Our operating expenses of \$5.5 million incurred in the third quarter of 2007 were consistent with our operating expense of \$5.2 million incurred in the immediately preceding quarter, with the increase being largely driven by legal fees incurred in connection with the Hansen litigation matter.

Other Income (Expense)

Net interest income decreased from about \$233,000 to \$93,690 between September 30, 2006 and 2007, respectively, which was attributable to a decrease in invested cash. Nearly all of the interest expense during the three months ended September 30, 2007, was incurred on our senior convertible promissory notes issued to Carilion Clinic on December 30, 2005. These notes have an aggregate outstanding principal of approximately \$5.0 million and accrue simple interest at a rate of 6.0% per year. During the three month period ended September 30, 2007, interest expense on such notes was approximately \$76,000. Interest income for the three months ended September 30, 2007, totaled approximately \$173,000. Finally, during the third quarter of 2007, we did not have an outstanding balance on our \$3.0 million line of credit and did not incur interest expense on that line of credit in the third quarter of 2007.

Nine Months Ended September 30, 2007 Compared to Nine Months Ended September 30, 2006

Revenues

Total revenues increased 53% to \$23.7 million for the nine months ended September 30, 2007, from \$15.5 million for the nine months ended September 30, 2006. The increase was due in part to increased product sales related to our Luna Technologies Division. Our acquisition of Luna Technologies in September 2005 and the subsequent product sales by that

Table of Contents

division are key elements of our strategic transition towards our goal of increased product sales revenues. We generated approximately \$6.7 million in product sales for the nine months ending September 30, 2007 as compared with \$2.5 million in the same period for 2006.

Growth in our technology development revenues also contributed to our overall growth in revenues for the third quarter of 2007 as compared with the third quarter of 2006. Technology development revenues increased 32% to \$17.1 million for the nine months ended September 30, 2007 from \$13.0 million for the corresponding 2006 period. This increase was primarily a result of a continued strong success in obtaining research contracts, an increase in the size of certain awards, and the addition of direct contract personnel.

Cost of Revenues

Cost of revenues increased 35% to \$14.6 million for the nine months ended September 30, 2007 from \$10.8 million for the corresponding 2006 period. The main component of this overall increase was increased costs of labor and materials related to increases in technology development revenue. New technology development cost of sales increases accounted for approximately \$2.3 million, or 61%, and product sales cost increases accounted for approximately \$1.5 million, or 39%, respectively, of the overall increase in costs of revenues.

Technology development costs increased 24% to \$11.9 million for the nine months ended September 30, 2007 from \$9.6 million in the same period in 2006. This increase was consistent with the 32% increase in our technology development revenues, and was comprised primarily of additional direct labor and the technology associated overhead related to research and development activities.

Our overall gross margin improved as compared with the first nine months of 2006. Our overall gross margin during the nine months ended September 30, 2007 was 39% compared to 30% during the same period in 2006. During the nine months ended September 30, 2007, technology development activity returned a gross margin of approximately 30% compared to 26% in the same period of 2006. Product sales activity returned a gross margin of 60% for the nine months ended September 30, 2007, compared to 53% for the same period in 2006. One of our objectives in seeking greater relative product sales is based on the goal of achieving higher margins to improve our overall profitability.

Operating Expense

Operating expense increased 37% to \$16.1 million for the nine months ended September 30, 2007 from \$11.8 million for the corresponding period in 2006. Much of the increase in the first nine months of 2007 as compared to the same period in 2006 was due to indirect expenses in connection with implementing our business plan relating to commercializing new products and increasing our product sales capabilities. Consistent with our strategy of building a growing portfolio of businesses and products, we were and are actively hiring additional staff with related recruitment and relocation charges, incurring legal and professional fees and implementing various internal changes to prepare and to strengthen our existing infrastructure and management resources as a result of becoming a public company. With the completion of our second round financing with Carilion Clinic in December 2005, and the proceeds from our IPO in June 2006, we gained the necessary resources to begin implementing many of these important changes to our business. We expect that our operating expenses will remain at these increased levels in the coming months due to our continued growth and development and compliance with the various regulatory requirements associated with being a public company.

Other Income (Expense)

Net interest income was \$0.3 million for the nine months ended September 30, 2006 and 2007, respectively, which was attributable to earnings on invested cash. Nearly all of the interest expense during the nine months ended September 30, 2007, was incurred on our senior convertible promissory notes issued to Carilion Clinic on December 30, 2005. These notes have an aggregate outstanding principal of approximately \$5.0 million and accrue simple interest at a rate of 6.0% per year. During the nine month period ended September 30, 2007, interest expense on such notes was approximately \$0.2 million. Interest income for the nine months ended September 30, 2007, totaled \$0.5 million. Finally, during the first nine months of 2007, we did not have an outstanding balance on our \$3.0 million line of credit, and therefore, did not incur interest expense on that line of credit.

Liquidity and Capital Resources

Prior to August 2005, our primary source of liquidity had been cash provided by operations, financing from the revolving credit facility, and divestitures of certain assets and businesses. In August 2005, we completed our first outside equity financing and raised \$7.0 million through an equity investment by Carilion Clinic. Carilion Clinic invested an additional \$8.0 million in December 2005 in the form of \$5.0 million in senior convertible promissory notes and \$3.0 million in additional equity. Our principal uses of cash have been to fund our expansion, including facilities, personnel, working capital and other capital expenditures, and to fund our costs of transition to a public company.

Table of Contents

We have a \$3.0 million senior secured revolving credit facility with First National Bank that is collateralized by a security interest in substantially all of our assets. The interest rate on borrowings under our secured revolving credit facility is equal to the prime rate, limited to no less than 6.0% and no greater than 10.0% per annum, with interest payable monthly. This agreement also provides a \$1.0 million sub-limit for letters of credit and currently expires June 30, 2008. The senior secured revolving credit facility contains covenants which require us to maintain \$1.0 to \$2.0 million in liquidity depending on our outstanding balance. Additionally, without First National Bank's prior approval, we may not make a direct loan to an affiliate or subsidiary of ours exceeding \$500,000 annually, guaranty the debt of our affiliate or subsidiary or incur debt in excess of \$200,000 with other third parties. Finally, we are obligated to continue to provide First National Bank an assignment of life insurance in a minimum amount of \$1.0 million on the life of Kent A. Murphy, covering our indebtedness to First National Bank. As of September 30, 2007, there was no outstanding borrowing on this credit line. With the exception of our obligations under the senior convertible promissory notes, the senior secured revolving credit facility and our capital lease, we have no other debt outstanding.

On June 2, 2006, the effective date of our initial public offering, we sold 3,500,000 shares of common stock at \$6.00 per share resulting in gross proceeds of \$21.0 million. In connection with this offering, we paid \$1.47 million in underwriting discounts and commissions and incurred other offering expenses of approximately \$1.66 million. The net proceeds from the offering were approximately \$17.87 million.

Discussion of Cash Flows

Recent Activity

We used approximately \$3.8 million and \$6.3 million of net cash from operations during the nine months ended September 30, 2007 and 2006, respectively. The decrease in cash used in operations resulted from a decrease of \$60,000 in net loss, offset by the \$3.0 million positive non-cash change for depreciation, amortization, and share-based compensation. Additionally, changes in working capital accounts used a net \$0.1 million in cash from operating activities for the nine months ended September 30, 2007 compared to \$1.5 million for the nine months ended September 30, 2006. The change in working capital accounts for the nine months ended September 30, 2007 includes a \$1.0 million increase in deferred revenue arising from the timing difference between receipt of cash and the recognition of revenue for certain long-term development contracts to be accounted for using the percentage of completion method.

Cash used in investing activities for the nine months ended September 30, 2007 related primarily to the purchase of property and equipment and legal fees associated with securing patent rights to certain technology. Our overall cash used in investing activities was \$1.6 million in the nine months ended September 30, 2007, compared to \$1.7 million in the corresponding September 30, 2006 period. In future months, we expect to maintain a lower rate of growth in net cash used in investing activities as we believe that we now have the necessary resources to begin and complete a number of longer-term investments in our growth.

Cash flows used by financing activities for the nine months ended September 30, 2007 was \$5,000, representing a decrease in cash flow from cash generated by financing activities for the nine months ended September 30, 2006. Cash generated by financing activities for the nine months ended September 30, 2006 consisted of proceeds from the issuance of common stock of \$17.9 million, related to our Initial Public Offering. We did not draw additional financing from our line of credit or other sources in the nine months ended September 30, 2007.

At September 30, 2007, total cash and cash equivalents were approximately \$12.5 million. We believe that our current cash on hand and cash available under our line of credit agreement will be sufficient to fund operations for the next 12 months.

Summary of Contractual Obligations

We lease our facilities in Blacksburg, Charlottesville, Danville, Hampton, McLean and Roanoke, Virginia under operating leases that expire on various dates through January 2014 or under a month-to-month arrangement. Upon expiration of the leases, we may exercise certain renewal options as specified in the leases.

We also lease certain computer equipment and software under capital lease agreements that expire through January 2010. The assets subject to these obligations are included in property and equipment on our consolidated balance sheet.

Our Luna Technologies Division has an agreement with a supplier to purchase tunable lasers and estimates its noncancellable obligation to be approximately \$1.3 million through 2008.

Table of Contents

In March 2004, we received a grant of \$0.9 million from the City of Danville, Virginia under a Grant Agreement to support the expansion of economic and commercial growth within the City. Under the Grant Agreement, we agreed to locate a nanomaterials manufacturing and research facility and maintain its operations in Danville until March 25, 2009. As of September 25, 2006, we had not fully met the capital expenditures and job milestones under this agreement, and, as a result, we may be obligated to repay the City of Danville a portion of the \$0.9 million in funds based on a formula of the pro rata shortfall of such expenditures and jobs falling below such required levels. Because of the failure to meet these milestones and the continuing obligation to maintain our investment and employees at this location through March 25, 2009, we currently have classified the full amount of the grant as a liability on our balance sheet in anticipation of potentially returning the funds.

Off-Balance Sheet Arrangements

We have no material off-balance sheet arrangements as defined in Regulation S-K 303(a)(4)(ii).

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

We do not use derivative financial instruments as a hedge against interest rate fluctuations, and, as a result, interest income earned on our cash and cash equivalents and short-term investments is subject to changes in interest rates. However, we believe that the impact of these fluctuations does not have a material effect on our financial position due to the immediate available liquidity or short-term nature of these financial instruments. As of September 30, 2007, we had \$12.5 million deposited in cash and cash equivalents bearing a weighted-average interest rate of approximately 5.0%.

Foreign Currency Exchange Rate Risk

Our product sales to foreign customers are denominated in U.S. dollars and we do not receive payments in foreign currency. As such, we are not directly exposed to currency gains or losses resulting from fluctuations in foreign exchange rates.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our Chief Executive Officer and our Chief Financial Officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Securities Exchange Act of 1934 (the Exchange Act) Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this report, have concluded that as of September 30, 2007, our disclosure controls and procedures were effective to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act (i) is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission and (ii) is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

We do not believe we have material weaknesses or significant deficiencies related to our policies and procedures that pertain to maintenance of records, authorizations of receipts and expenditures, or prevention or timely detection of unauthorized acquisition, use, or disposition of our assets. However, we have not performed specific tests to determine the effectiveness of key controls within these policies and procedures. We intend to monitor those policies and procedures in connection with the establishment of a formally documented system of internal control. We are continuing documentation of our internal controls processes in order to identify additional areas for improvement as well as in anticipation of our need to comply with the requirements of the Sarbanes-Oxley Act of 2002.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we may become involved in litigation in relation to claims arising out of our operations in the normal course of business. While management currently believes the amount of ultimate liability, if any, with respect to these actions will not materially affect our financial position, results of operations, or liquidity, the ultimate outcome of any litigation is uncertain. Were an unfavorable outcome to occur, or if protracted litigation were to ensue, the impact could be material to us.

Table of Contents

On June 18, 2007, we filed a lawsuit against Goodman & Company, L.L.P (Goodman) in the Superior Court of the District of Columbia seeking monetary damages for breach of contract and professional negligence. These claims are based on Goodman s actions prior to our initial public offering and do not have any relationship to our current or prior period financial statements. We have agreed to not serve the lawsuit to provide an opportunity for the parties to resolve the dispute before initiation of court proceedings.

On June 22, 2007, Hansen Medical, Inc. (Hansen) filed a lawsuit against us in California State Court, Santa Clara County, alleging misappropriation of trade secrets, unfair competition, breach of contract, and breach of the implied covenant of good faith and fair dealing. The claims allegedly stem from our past relationship with Hansen and our past and future relationship with Intuitive Surgical, Inc. (Intuitive). The lawsuit makes an unspecified claim for damages, however Hansen has not indicated how it will substantiate such damages, and we are unable to reasonably estimate the amount of damages, if any, that Hansen will seek. In addition, Hansen may seek equitable relief, including, for example, an injunction to prevent us from misusing Hansen s trade secrets or proprietary information or an injunction to prevent us from working with Intuitive. This litigation is in its early stages. We believe Hansen s allegations are without merit and we intend to vigorously defend ourselves in this lawsuit. Additionally, on October 12, 2007, we filed a cross-claim against Hansen alleging misappropriation of trade secrets, unfair competition, breach of contract, and breach of the implied covenant of good faith and fair dealing and seeking a declaratory judgment as to the parties rights and obligations. Our cross-claim seeks damages and equitable relief. However, we cannot predict the ultimate outcome of this litigation, and we are unable to estimate any potential liability we may incur.

ITEM 1A. RISK FACTORS

You should carefully consider the risks described below before deciding whether to invest in our common stock. The risks described below are not the only ones we face. Additional risks not presently known to us or that we currently believe are immaterial may also impair our business operations and financial results. If any of the following risks actually occurs, our business, financial condition or results of operations could be adversely affected. In such case, the trading price of our common stock could decline and you could lose all or part of your investment. Our filings with Securities and Exchange Commission also contain forward-looking statements that involve risks or uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks we face described below.

RISKS RELATING TO OUR BUSINESS

If we are unable to manage our growth effectively, our revenue and net loss could be adversely affected.

While historically we have developed and commercialized only a few products at a time, we plan to grow by developing and commercializing multiple products concurrently across many industries, technologies and markets. Our ability to grow by developing and commercializing multiple products simultaneously requires that we manage a diverse range of projects, and expand our personnel resources. Our inability to do any of these could prevent us from successfully implementing our growth strategy, and our revenues and profits could be adversely affected.

To advance the development of multiple promising potential products concurrently, we need to manage effectively the logistics of maintaining the requisite corporate, operational, administrative and financing functions for each of these product opportunities. Potentially expanding our operations into new geographic areas and relying on multiple facilities to develop and manufacture different products concurrently pose additional challenges. We have little experience in managing these functions simultaneously for multiple projects in development or in building new infrastructure and integrating the operations of various facilities. If we cannot manage this process successfully, we may be subject to operating difficulties, additional expenditures and limited revenue growth.

We need to expand our personnel resources to grow our business effectively. We believe that sustained growth at a higher rate will place a strain on our management, as well as on our other human resources. To manage this growth, we must continue to attract and retain qualified management, professional, scientific and technical and operating personnel. During the most recently completed calendar quarter, the labor market, particularly for highly-specialized scientists and engineers remained tight. If we are unable to recruit a sufficient number of qualified personnel, we may be unable to staff and manage projects adequately, which may slow the rate of growth of our technology development revenue or our product development efforts.

We have incurred recent losses, and because our strategy for expansion may be costly to implement, we may experience continuing losses which may be significant.

Table of Contents

We incurred consolidated net losses of approximately \$9.4 million for the year ended December 31, 2006 and \$6.7 million for the nine months ending September 30, 2007. We expect to continue to incur significant additional expenses as we expand our business, including increased expenses for research and development, sales and marketing, manufacturing, finance and accounting personnel and expenses associated with being a public company. We may also grow our business in part through acquisitions of additional companies and complementary technologies which could cause us to incur greater than anticipated transaction expenses, amortization or write-offs of intangible assets and other acquisition-related expenses. As a result, we expect that we may likely continue to incur losses for the foreseeable future, and these losses could be substantial.

Because of the numerous risks and uncertainties associated with our business and our expansion strategy, we are unable to predict when or if we will be able to achieve profitability again. If our revenues do not increase, or if our expenses increase at a greater rate than our revenues, we will continue to experience losses. Even if we do achieve profitability, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

If we cannot successfully transition our revenue mix from technology development revenues to product sales and license revenues, we may not be able to fully execute our business model or grow our business.

Our business model and future growth depend on our ability to transition to a revenues mix that contains significantly larger product sales and license revenues components. Product sales and license revenues potentially offer greater scalability and higher gross margins than services-based technology development revenues. Our current plan is to increase our portfolio of commercial products and, accordingly, we expect that our future product sales and license revenues will represent a larger percentage of total revenues. However, if we are unable to develop and grow our product sales and license revenues to augment our technology development revenues, our ability to execute our business model or grow our business could suffer.

We may not be successful in identifying market needs for new technologies and developing new products to meet those needs.

The success of our business model depends on our ability to identify correctly market needs for new technologies. We intend to identify new market needs, but we may not always have success in doing so, in part, because our technology development largely centers on identification and development of unproven technologies, often for new or emerging markets. Furthermore, we must identify the most promising technologies from a sizable pool of projects. If our commercialization strategy process fails to identify projects with commercial potential or if management does not ensure that such projects advance to the commercialization stage, we may not successfully commercialize new products and grow our revenues.

Our growth strategy requires that we not only identify new technologies that meet market needs, but that we also develop successful commercial products that address those needs. We face several challenges in developing successful new products. Many of our existing products and those currently under development-including our Trimetasphere[®] carbon nanomaterials, which are nanomaterials in the form of a carbon sphere with three metal atoms enclosed inside-are technologically innovative and require significant and lengthy product development efforts. These efforts include planning, designing, developing and testing at the technological, product and manufacturing-process levels. These activities require us to make significant investments. Although there are many potential applications for our technologies, our resource constraints require us to focus on a limited number of products and to forgo other opportunities. We expect that one or more of the potential products we choose to develop will not be technologically feasible or will not achieve commercial acceptance, and we cannot predict which, if any, of our products we will successfully develop or commercialize.

The technologies we research and develop are new and steadily changing and advancing. The products that are derived from these technologies may not be applicable or compatible with the state of technology or demands in existing markets. Our existing products and technologies may become uncompetitive or obsolete if our competitors adapt more quickly than we do to new technologies and changes in customers requirements. Furthermore, we may not be able to identify if and when new markets will open for our products given that future applications of any given product may not be readily determinable, and we cannot reasonably estimate the size of any markets that may develop. If we are not able to successfully develop new products, we may be unable to increase our product revenues.

Our failure to attract, train and retain skilled employees would adversely affect our business and operating results.

The availability of highly trained and skilled technical and professional personnel is critical to our future growth and profitability. Competition for scientists, engineers, technicians and professional personnel is intense and competitors aggressively recruit key employees. In the past, we have experienced difficulties in recruiting and hiring these personnel as a result of the tight labor market in certain fields. This fact, combined with our growth strategy and future needs for additional experienced personnel, particularly in highly specialized areas such as nanomaterial manufacturing and innovative ultrasound technologies, may make it more difficult to meet all of our needs for these employees in a timely

Edgar Filing: LUNA INNOVATIONS INC - Form 10-Q

manner. Although we intend to continue to devote significant resources to recruit, train and retain qualified employees, we may not be able to attract and retain these employees, especially in technical fields where the supply of experienced qualified candidates is limited. Any failure to do so would have an adverse effect on our business.

Table of Contents

In addition, our future success depends in a large part upon the continued service of key members of our senior management team. In particular, our Chairman, CEO and founder, Kent A. Murphy, Ph.D., is essential to our overall management as well as the development of our technologies, our culture and our strategic direction. All of our executive officers and key employees are at-will employees, and, except with respect to Kent A. Murphy, Ph.D., we do not maintain any key-person life insurance policies. The loss of any of our management or key personnel could seriously harm our business.

We rely and will continue to rely on contract research, including government-funded research contracts, for a significant portion of our revenues. A decline in government funding of existing or future government research contracts, including Small Business Innovation Research (or SBIR) revenues, could adversely affect our revenues and cash flows and our ability to fund our growth.

Technology development revenue, which consists primarily of government-funded research, accounted for approximately 72% and 84% of our consolidated total revenues for the nine months ended September 30, 2007 and 2006, respectively. As a result, we are vulnerable to adverse changes in our revenues and cash flows if a significant number of our research contracts and subcontracts are simultaneously delayed or canceled for budgetary, performance or other reasons. The U.S. government, for example, may cancel these contracts at any time without cause and without penalty or may change its requirements, programs or contract budget, any of which could reduce our revenues and cash flows from U.S. government research contracts. Our revenues and cash flows from U.S. government research contracts and subcontracts could also be reduced by declines or other changes in U.S. defense, homeland security and other federal agency budgets. In addition, we compete as a small business for some of these contracts, and in order to maintain our eligibility to compete as a small business, we (together with any affiliates) must continue to meet size and revenue limitations established by the U.S. government.

In addition to contract cancellations and changes in agency budgets, our future financial results may be adversely affected by curtailment of the U.S. government's use of contract research providers, including curtailment due to government budget reductions and related fiscal matters. These or other factors could cause U.S. defense and other federal agencies to conduct research internally rather than through commercial research organizations, to reduce their overall contract research requirements or to exercise their rights to terminate contracts. Any of these actions could limit our ability to obtain new contract awards and adversely affect our revenues and cash flows and our ability to fund our growth.

We also derive a significant portion of our technology development revenues from SBIR contracts. SBIR revenues accounted for approximately 52% and 65% of our consolidated total revenues for the three months ended September 30, 2007 and 2006, respectively. Contract research, including SBIR, will remain a significant portion of our consolidated total revenues for the foreseeable future. Our strategy for developing innovative technologies and products depends in large part on our ability to continue to enter into and generate revenues from non-SBIR contract research.

Our contract research customer base includes government agencies, corporations and academic institutions. Our customers are not obligated to extend their agreements with us. In addition, we may not be successful in securing future contracts. Our customers' priorities regarding funding for certain projects may change and funding resources may no longer be available at previous levels.

We rely and will continue to rely on contracts and grants awarded under the SBIR program for a significant portion of our revenues. A finding by the Small Business Administration, or SBA, that we no longer qualify to receive SBIR funding could adversely affect our business.

We may not qualify to participate in the Small Business Administration's, or SBA's, SBIR program or receive new SBIR awards from federal agencies in the future. In order to qualify for SBIR contracts and grants, at least 51% of our equity must be owned and controlled by U.S. citizens or permanent resident aliens, or by another entity that is at least 51% owned or controlled by U.S. citizens or permanent resident aliens, and we must have 500 or fewer employees. These eligibility criteria are applied as of the time of the award of a contract or grant. In determining whether we satisfy the 51% equity ownership requirement, agreements to merge, stock options, convertible debt and other similar instruments are given present effect by the SBA, as though the underlying securities were actually issued unless the exercisability or conversion of such securities is speculative, remote or beyond the control of the security holder. We therefore believe our outstanding options and warrants held by eligible individuals may be counted as, and our convertible debt may be excluded from, outstanding equity for purposes of meeting the 51% equity ownership requirement.

Table of Contents

We believe that we are currently in compliance with the SBIR eligibility criteria but we cannot provide assurance that the SBA will interpret its regulations in our favor. As of December 31, 2006, giving present effect to our outstanding options, we estimate that at least approximately 58% of our equity is owned by U.S. citizens or permanent residents. We must be able to certify that we meet the SBIR ownership and size requirements as of the time we enter into each SBIR contract or grant, and SBA may review our size status in connection with each SBIR contract or grant. As we grow our business, it is foreseeable that we will eventually exceed the SBIR eligibility limitations and we may need to find other sources to fund our research and development efforts. If we are unsuccessful in obtaining additional contracts or funding grants because we cannot meet the eligibility requirements or if our customers decide to reduce or discontinue support of our products, we may be required to seek alternative sources of revenues or capital.

The SBA could determine that, as a result of Carilion Clinic's equity ownership, the number of our employees exceeds the size limitation placed on SBA contract and SBIR grant recipients, and therefore we will not be eligible to receive future SBA contracts and SBIR grants.

In addition to the U.S. ownership eligibility criteria discussed above, to be eligible for SBA contracts and SBIR grants, the number of our employees including those of any entities that are considered to be affiliated with us, cannot exceed 500. As of September 30, 2007, we, including all of our divisions, had approximately 217 full and part time employees. However, in determining whether we are affiliated with any other entity, the SBA analyzes whether another entity controls or has the power to control us. If the SBA determines that another entity controls or has the power to control us, it will aggregate that entity's employees (and the employees of its subsidiaries and affiliates) with our own for purposes of applying the 500 employee test.

The SBA may make an affiliation determination based on stock ownership. For example, the SBA may presume that two or more entities have the power to control a company if the entities each own, control or has the power to control, less than 50 percent of the company's stock, such minority holdings are equal or approximately equal in size, and the aggregate of the minority holdings is large as compared to any other stock holding. However, this presumption may be rebutted by showing that such control or power to control does not in fact exist. As of September 30, 2007, Carilion Clinic held approximately 21.6% of our outstanding common stock, and Dr. Kent Murphy held approximately 25.6% of our outstanding common stock. Thus, applying the criteria stated above, the SBA could find that both Carilion Clinic and Dr. Murphy own less than 50% of the stock, their percentages are roughly equal, and their respective percentages are large compared to any other stock holding. We believe that the relative beneficial ownership of our individual stockholders rebuts the presumption of control by Carilion Clinic because the shares held by our executive officers and directors constitute the controlling interest in us. However, if the SBA were to make a determination that we are affiliated with Carilion Clinic, we would exceed the size limitations as Carilion Clinic has over 500 employees, and we therefore would lose eligibility for new SBA contracts, public contracts, grants and other awards that are set aside for small businesses, including SBIR grants.

We might require additional capital to support business growth, and this capital might not be available.

We intend to continue to make investments to support our business growth and may require additional funds to respond to business challenges, including the need to develop new products or enhance our existing products, enhance our operating infrastructure, complete our development activities, build our commercial scale manufacturing facilities and acquire complementary businesses and technologies. In 2006, we had a net loss of \$9.4 million and used \$9.1 million in cash for operations in addition to \$3.4 million cash used for investing activities. For the third quarter ended September 30, 2007, we had a net loss of \$1.8 million, and used \$3.8 million in cash for operations in addition to \$1.6 million used for investing activities. Our balance of cash and cash equivalents as of September 30, 2007, was \$12.5 million. In the future we may need to engage in equity or debt financings to secure additional funds to support our operations and investments in new products.

If we raise additional funds through issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences and privileges superior to those of holders of our common stock, including shares of common stock sold in our initial public offering. Furthermore, such financings may jeopardize our ability to apply for SBIR grants or qualify for SBIR contracts or grants, and our dependence on SBIR grants may restrict our ability to raise additional outside capital. In addition, we may not be able to obtain continued SBIR funding, or other additional financing on terms favorable to us, if at all. In order to retain SBIR eligibility, we may be restricted in our ability to raise certain forms of equity capital from institutional investors. For example, in connection with the closing of our financing with Carilion Clinic on December 30, 2005, we were not able to raise all proceeds through the issuance of equity without potentially jeopardizing our SBIR eligibility. We therefore elected to issue debt in the amount of \$5.0 million of the total \$8.0 million raised in such financing to maintain SBIR eligibility. Under the terms of these notes, we agreed that we will not draw down any amount under our existing senior secured credit facility with First National Bank or incur additional indebtedness other than under certain limited conditions. In addition, if we lose eligibility or elect to no longer compete for SBIR contracts prior to December 30, 2009, the holder of our \$5.0 million senior convertible promissory notes has the right, at its discretion, to convert some or all of the principal and interest amounts into shares of our common stock, which would result in further dilution to our existing stockholders.

Table of Contents

If we are unable to obtain adequate financing or financing on terms satisfactory to us, when we require it, our ability to continue to support our business growth and to respond to business challenges could be significantly limited.

If we are unable to secure third-party reimbursement for our healthcare products, including our EDAC QUANTIFIER and EN-TACT medical devices, our revenue and net loss could be adversely affected.

In both the United States and foreign markets where we intend to sell our medical products, third-party payors such as the government and health insurance companies are generally responsible for hospital and doctor reimbursement for medical products and services. Governments and insurance companies carefully review and increasingly challenge the prices charged for medical products and services. Reimbursement rates from private insurance companies vary depending on the procedure performed, the third party involved, the insurance plan involved, and other factors. In the United States, reimbursement for medical procedures under the Medicare and Medicaid programs is administered by Centers for Medicare & Medicaid Services. Medicare reimburses both hospitals and physicians a pre-determined, fixed amount based on the procedure performed. This fixed amount is paid regardless of the actual costs incurred by the hospital or physician in furnishing the care and is often unrelated to the specific devices used in that procedure. Thus, any reimbursements that hospitals or physicians obtain for using our medical products will generally have to cover any additional costs that hospitals incur in purchasing such products.

Hospitals and medical centers to which we intend to sell our EDAC QUANTIFIER product typically bill the services performed with our products to various third-party payors, such as Medicare, Medicaid and other government programs and private insurance plans. If hospitals do not obtain sufficient reimbursement from third-party payors for procedures performed with our products, or if governmental and private payors policies do not permit reimbursement for services performed using our products, demand for our product may be negatively impacted.

In countries outside the United States, reimbursement is obtained from various sources, including governmental authorities, private health insurance plans and labor unions. To sell our product in foreign markets, we may need to seek international reimbursement approvals. We cannot be certain whether such required approvals will be obtained in a timely manner or at all.

Furthermore, any regulatory or legislative developments in domestic or foreign markets that eliminate or reduce reimbursement rates for procedures performed with our products could harm our ability to sell our products or cause downward pressure on the prices of our products, either of which would have a negative effect on our product revenue and net loss.

We face and will face substantial competition in several different markets that may adversely affect our results of operations.

We face or will face substantial competition from a variety of companies in several different markets. Our competitors in contract research include, but are not limited to, companies such as General Dynamics Corporation, Lockheed Martin Corporation, SAIC, Inc. and SRA International, Inc. In the instrumentation and test and measurement products market, our competitors include, but are not limited to, large companies such as Agilent Technologies, Inc., Analog Devices, Inc., Freescale Semiconductor, Inc., JDS Uniphase Corp., Robert Bosch GmbH and Silicon Sensing, as well as emerging companies. In addition, in the MRI contrast agent market our competitors include Amersham Plc, Berlex Laboratories, Inc., Bracco Diagnostics, Inc., and Mallinckrodt Inc.

The products that we have developed or are currently developing will compete with other technologically innovative products as well as products incorporating conventional materials and technologies. We expect that our products will face competition in a wide range of industries, including telecommunications, industrial instrumentation, healthcare, military and security applications.

Many of our competitors have longer operating histories, greater name recognition, larger customer bases and significantly greater financial, sales and marketing, manufacturing, distribution, technical and other resources than we do. These competitors may be able to adapt more quickly to new or emerging technologies and changes in customer requirements. In addition, current and potential competitors have established or may establish financial or strategic relationships among themselves or with existing or potential customers or other third parties. Accordingly, new competitors or alliances among competitors could emerge and rapidly acquire significant market share. We cannot assure you that we will be able to compete successfully against current or new competitors, in which case our net revenues may fail to increase or may decline.

Table of Contents

We may be obligated to repay part of the proceeds received in connection with a grant from the City of Danville, Virginia, for failing to make certain agreed upon expenditures and failing to meet certain employment obligations.

In March 2004, we received a grant of \$900 thousand from the City of Danville, Virginia under a Grant Agreement to support the expansion of economic and commercial growth within the City. Under the Grant Agreement, we agreed to locate a nanomaterials manufacturing and research facility and maintain its operations in Danville until March 25, 2009. Our obligations under this Grant Agreement require us to incur significant expenditures in order to retain such proceeds from the grant. Specifically, we agreed under the Grant Agreement to invest at least \$5.2 million in capital equipment expenditures and \$1.2 million in certain facilities by September 25, 2006 and to maintain such investments in our Danville facility until March 25, 2009. We also agreed to create by September 25, 2006 at least 54 new full-time jobs at the Danville facility at an average annual wage of at least \$39 thousand plus benefits, and to maintain these jobs at such facility until March 25, 2009. These contractual requirements obligate us to an annual payroll obligation exceeding \$2.0 million until March 25, 2009. To the extent such hiring results in salaries in excess of the required minimum wages, our annual payroll obligation could be substantially greater than \$2.0 million. As of September 25, 2006, we had not fully met these capital expenditures and job milestones, and, as a result, we may be asked to repay the City of Danville a portion of the \$900 thousand in funds based on a formula of the pro rata shortfall of such expenditures and jobs falling below such required levels. Because of the failure to meet these milestones and the continuing obligation to maintain our investment and employees at this location through March 25, 2009, we currently have classified the full amount of the grant as a liability on our balance sheet in anticipation of potentially returning the funds.

We have limited experience manufacturing our products in commercial quantities in a cost-effective manner, which could adversely impact our business.

We have produced most of our products on a custom order basis rather than pursuant to large contracts that require production on a large volume basis. Accordingly, other than the commercial manufacture of products by our Luna Technologies Division, we have no experience manufacturing products in large volume. Because our experience in large scale manufacturing is limited, we may encounter unforeseen difficulties in our efforts to manufacture other products or materials in commercial quantities or have to rely on third-party contractors over which we do not have direct control to manufacture our products. For example, we have engaged a third-party contract manufacturer to produce our line of tunable lasers. We also may need to develop or in-license Trimetasphere® nanomaterial purification and isolation technology, which would result in manufacturing delays or shortfalls. We may also encounter difficulties and delays in manufacturing our products for the following reasons:

we plan to expand our manufacturing operations, and our production processes may have to change to accommodate this growth;

to increase our manufacturing output significantly, we will have to attract and retain qualified employees, who are in short supply, for the assembly and testing operations;

we might have to sub-contract to outside manufacturers which might limit our control of costs and processes; and

our manufacturing operations may have to comply with government specifications.

If we are unable to keep up with demand for our products, our revenue growth could be impaired, market acceptance for our products could be adversely affected and our customers might instead purchase our competitors' products. Moreover, failure to develop and maintain a U.S. market for goods developed with U.S. government-licensed technology may result in the cancellation of the relevant U.S. government licenses. Our inability to manufacture our products successfully would have a material adverse effect on our revenues.

Even if we are able to manufacture our products on a commercial scale, the cost of manufacturing our products may be higher than we expect. If the costs associated with manufacturing are not significantly less than the prices at which we can sell our products, we may not be able to operate at a profit.

We depend on third-party vendors for specialized components in our manufacturing operations, making us vulnerable to supply shortages and price fluctuations that could harm our business.

Edgar Filing: LUNA INNOVATIONS INC - Form 10-Q

We primarily rely on third-party vendors for the manufacture of the specialized components used in our products. Although we do not have any sole source suppliers of materials, the highly specialized nature of our supply requirements poses risks that we may not be able to locate additional sources of the specialized components required in our business. For example, we are aware of only two manufacturers that produce the special lasers used in our optical test equipment. Moreover, none of these third-party vendors is obligated to continue to supply us with components. Our reliance on these vendors subjects us to a number of risks that could impact our ability to manufacture our products and harm our business, including interruption of supply.

Table of Contents

Any significant delay or interruption in the supply of components, or our inability to obtain substitute components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and harm our business.

Our nanotechnology-enabled products are new and may be, or may be perceived as being, harmful to human health or the environment.

While none of our current products are known by us to be hazardous or subject to environmental regulation, it is possible our current or future products, particularly carbon-based nanomaterials, may become subject to environmental regulation. We intend to develop and sell carbon-based nanomaterials as well as nanotechnology-enabled products, which are products that include nanomaterials as a component to enhance those products' performance. Nanomaterials and nanotechnology-enabled products have a limited historical safety record. Because of their size or shape or because they may contain harmful elements, such as gadolinium and other rare-earth metals, our products could pose a safety risk to human health or the environment. These characteristics may also cause countries to adopt regulations in the future prohibiting or limiting the manufacture, distribution or use of nanomaterials or nanotechnology-enabled products. Such regulations may inhibit our ability to sell some products containing those materials and thereby harm our business or impair our ability to develop commercially viable products.

The subject of nanotechnology has received negative publicity and has aroused public debate. Government authorities could, for social or other purposes, prohibit or regulate the use of nanotechnology. Ethical and other concerns about nanotechnology could adversely affect acceptance of our potential products or lead to government regulation of nanotechnology-enabled products.

We face risks associated with our international business.

Our Products Division currently conducts business internationally and we might considerably expand our international activities in the future. Our international business operations are subject to a variety of risks associated with conducting business internationally, including:

having to comply with U.S. export control regulations and policies that restrict our ability to communicate with non-U.S. employees and supply foreign affiliates and customers;

changes in or interpretations of foreign regulations that may adversely affect our ability to sell our products, perform services or repatriate profits to the United States;

the imposition of tariffs;

hyperinflation or economic or political instability in foreign countries;

imposition of limitations on or increase of withholding and other taxes on remittances and other payments by foreign subsidiaries or joint ventures;

conducting business in places where business practices and customs are unfamiliar and unknown;

the imposition of restrictive trade policies;

the imposition of inconsistent laws or regulations;

the imposition or increase of investment and other restrictions or requirements by foreign governments;

uncertainties relating to foreign laws and legal proceedings;

having to comply with a variety of U.S. laws, including the Foreign Corrupt Practices Act; and

having to comply with licensing requirements.

We do not know the impact that these regulatory, geopolitical and other factors may have on our international business in the future.

RISKS RELATING TO OUR REGULATORY ENVIRONMENT

As a provider of contract research to the U.S. government, we are subject to federal rules, regulations, audits and investigations, the violation or failure of which could adversely affect our business.

We must comply with and are affected by laws and regulations relating to the award, administration and performance of U.S. government contracts. Government contract laws and regulations affect how we do business with our government customers and, in some instances, impose added costs on our business. A violation of specific laws and regulations could result in the imposition of fines and penalties or the termination of our contracts or debarment from bidding on contracts. In

Table of Contents

some instances, these laws and regulations impose terms or rights that are more favorable to the government than those typically available to commercial parties in negotiated transactions. For example, the U.S. government may terminate any of our government contracts and, in general, subcontracts, at their convenience, as well as for default based on performance.

In addition, U.S. government agencies, including the Defense Contract Audit Agency and the Department of Labor, routinely audit and investigate government contractors. These agencies review a contractor's performance under its contracts, cost structure and compliance with applicable laws, regulations and standards. The U.S. government also may review the adequacy of, and a contractor's compliance with, its internal control systems and policies, including the contractor's purchasing, property, estimating, compensation and management information systems. Any costs found to be improperly allocated to a specific contract will not be reimbursed, while such costs already reimbursed must be refunded. If an audit uncovers improper or illegal activities, we may be subject to civil and criminal penalties and administrative sanctions, including termination of contracts, forfeiture of profits, suspension of payments, fines and suspension or prohibition from doing business with the U.S. government. In addition, our reputation could suffer serious harm if allegations of impropriety were made against us.

In March 2006, our senior management became aware that seven foreign national citizens who were working for us had access to International Traffic in Arms Regulations, or ITAR, controlled technical data. Such data may be deemed to have been exported/disclosed to certain of these individuals without the required export licenses. Following this discovery, in an effort to ensure full compliance with ITAR we submitted voluntary disclosure of these circumstances to the U.S. Department of State in April 2006. In December 2006, we received a letter from U.S. Department of State stating that they have completed their review of our voluntary disclosure and were closing this case without taking civil penalty action authorized under ITAR Sec. 127.10. The government, however, reserved the right to reopen the case if the circumstances warrant.

In addition to the risk of government audits and investigations, U.S. government contracts and grants impose requirements on contractors and grantees relating to ethics and business practices, which carry civil and criminal penalties ranging from monetary fines, assessments, loss of the ability to do business with the U.S. government and certain other criminal penalties.

We may also be prohibited from commercially selling certain products that we develop under our Technology Development Division or related products based on the same core technologies if the U.S. government determines that the commercial availability of those products could pose a risk to national security. For example, certain of our wireless technologies have been classified as secret by the U.S. government and as a result we cannot sell them commercially. Any of these determinations would limit our ability to generate product sales and license revenues.

Our healthcare and medical products are subject to a lengthy and uncertain domestic regulatory approval process. If we do not obtain and maintain the necessary domestic regulatory approvals or clearances, we will not be able to market and sell our products for clinical use in the United States.

Certain of our current and potential products will require regulatory clearances or approvals prior to commercialization. In particular, our Trimetasphere® nanomaterial-based MRI contrast agent and our EDAC and EN-TACT ultrasound diagnostic devices for measuring certain medical conditions will be considered a drug and medical devices, respectively, under the Federal Food, Drug & Cosmetic Act, or FDC Act. Drugs and some medical devices are subject to rigorous preclinical testing and other approval requirements by the Food and Drug Administration, or FDA, pursuant to the FDC Act, and regulations under the FDC Act, as well as by similar health authorities in foreign countries. Various federal statutes and regulations also govern or influence the testing, manufacturing, safety, labeling, packaging, advertising, storage, registration, listing and recordkeeping related to marketing of these products. The process of obtaining these clearances or approvals and the subsequent compliance with appropriate federal statutes and regulations require the expenditure of substantial resources. We cannot be certain that any required FDA or other regulatory approval will be granted or, if granted, will not be withdrawn. Our failure to obtain the necessary regulatory approvals, or our failure to obtain them in a timely manner, will prevent or delay our commercialization of new products and our business or our stock price could be adversely affected.

In general, the FDA regulates the research, testing, manufacturing, safety, labeling, storage, record keeping, promotion, distribution and production of medical devices in the United States to ensure that medical products distributed domestically are safe and effective for their intended uses. In order for us to market our EDAC and EN-TACT products for clinical use in the United States, we generally must first obtain clearance from the FDA pursuant to Section 510(k) of the Food, Drug, and Cosmetic Act. Clearance under Section 510(k) requires demonstration that a new device is substantially equivalent to another device with 510(k) clearance or grandfather status. If we significantly modify our products after they receive FDA clearance, the FDA may require us to submit a separate 510(k) or premarket approval, or PMA, application for the modified product before we are permitted to market the products in the U.S. In addition, if we develop products in the future that are not considered to be substantially equivalent to a device with 510(k) clearance or grandfather status, we will be required to obtain FDA approval by submitting a PMA.

Table of Contents

The FDA may not act favorably or quickly in its review of our 510(k) or PMA submissions, or we may encounter significant difficulties and costs in our efforts to obtain FDA clearance or approval, all of which could delay or preclude sale of new products for clinical use in the United States. Furthermore, the FDA may request additional data or require us to conduct further testing, or compile more data, including clinical data and clinical studies, in support of a 510(k) submission. The FDA may also, instead of accepting a 510(k) submission, require us to submit a PMA, which is typically a much more complex and burdensome application than a 510(k). To support a PMA, the FDA would likely require that we conduct one or more clinical studies to demonstrate that the device is safe and effective. We may not be able to meet the requirements to obtain 510(k) clearance or PMA approval, or the FDA may not grant any necessary clearances or approvals. In addition, the FDA may place significant limitations upon the intended use of our products as a condition to a 510(k) clearance or PMA approval. Product applications can also be denied or withdrawn due to failure to comply with regulatory requirements or the occurrence of unforeseen problems following clearance or approval. Any delays or failure to obtain FDA clearance or approvals of new products we develop, any limitations imposed by the FDA on new product use, or the costs of obtaining FDA clearance or approvals could have a material adverse effect on our business, financial condition and results of operations.

Complying with FDA regulations is an expensive and time-consuming process. Our failure to comply fully with such regulations could subject us to enforcement actions.

Our commercially distributed medical device products will be subject to numerous post-market regulatory requirements, including the following:

Quality System Regulation, or QSR, which requires manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures during the manufacturing process;

labeling regulations;

the FDA's general prohibition against false or misleading statements in the labeling or promotion of products for unapproved or off-label uses;

the Reports of Corrections and Removals regulation, which requires that manufacturers report to the FDA recalls and field corrective actions taken to reduce a risk to health or to remedy a violation of the FDC Act that may pose a risk to health; and

the Medical Device Reporting regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur.

We will also become subject to inspection and marketing surveillance by the FDA to determine our compliance with regulatory requirements. If the FDA finds that we have failed to comply, it can institute a wide variety of enforcement actions, ranging from a regulatory letter to a public warning letter to more severe civil and criminal sanctions. Our failure to comply with applicable requirements could lead to an enforcement action that may have an adverse effect on our financial condition and results of operations.

If our manufacturing facilities do not meet Federal, State or foreign country manufacturing standards, we may be required to temporarily cease all or part of our manufacturing operations, which would result in product delivery delays and negatively impact revenue.

Our manufacturing facilities are subject to periodic inspection by regulatory authorities and our operations will continue to be regulated by the FDA for compliance with Good Manufacturing Practice requirements contained in the FDA's Quality System Regulations, or QSR. We are also required to comply with International Organization for Standardization, or ISO, quality system standards in order to produce products for sale in Europe. If we fail to continue to comply with Good Manufacturing Practice requirements or ISO standards, we may be required to cease all or part of our medical product operations until we comply with these regulations. Obtaining and maintaining such compliance is difficult and costly. We cannot be certain that our facilities will be found to comply with Good Manufacturing Practice requirements or ISO standards in future inspections and audits by regulatory authorities.

Our medical products are subject to various international regulatory processes and approval requirements. If we do not obtain and maintain the necessary international regulatory approvals, we may not be able to market and sell our medical products in foreign countries.

Table of Contents

To be able to market and sell our products in other countries, we must obtain regulatory approvals and comply with the regulations of those countries. These regulations, including the requirements for approvals and the time required for regulatory review, vary from country to country. Obtaining and maintaining foreign regulatory approvals are expensive, and we cannot be certain that we will receive regulatory approvals in any foreign country in which we plan to market our products. If we fail to obtain regulatory approval in any foreign country in which we plan to market our products, our ability to generate revenue will be harmed.

The European Union requires that manufacturers of medical products obtain the right to affix the CE mark to their products before selling them in member countries of the European Union. The CE mark is an international symbol of adherence to quality assurance standards and compliance with applicable European medical device directives. In order to obtain the right to affix the CE mark to products, a manufacturer must obtain certification that its processes meet certain European quality standards.

We have not yet received permission to affix the CE mark to our medical products. We do not know whether we will be able to obtain permission to affix the CE mark for new or modified products. If we are unable to obtain permission to affix the CE mark to our products, we will not be able to sell our products in member countries of the European Union.

We are subject to significant foreign and domestic government regulations, including environmental and health and safety regulations, and failure to comply with these regulations could harm our business.

Our facilities and current and proposed activities involve the use of a broad range of materials that are considered hazardous under applicable laws and regulations. Accordingly, we are subject to a number of foreign, federal, state, and local laws and regulations relating to health and safety, protection of the environment, and the storage, use, disposal of, and exposure to, hazardous materials and wastes. We could incur costs, fines and civil and criminal penalties, personal injury and third party property damage claims, or could be required to incur substantial investigation or remediation costs if we were to violate or become liable under environmental, health and safety laws. Moreover, a failure to comply with environmental laws could result in fines and the revocation of environmental permits, which could prevent us from conducting our business. Liability under environmental laws can be joint and several and without regard to fault. There can be no assurance that violations of environmental health and safety laws will not occur in the future as a result of the inability to obtain permits, human error, equipment failure or other causes. Environmental laws could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations, which could harm our business. Accordingly, violations of present and future environmental laws could restrict our ability to expand facilities, pursue certain technologies, and could require us to acquire costly equipment, or to incur potentially significant costs to comply with environmental regulations.

The European Union Directive 2002/96/EC on Waste Electrical and Electronic Equipment, known as the WEEE Directive, requires producers of certain electrical and electronic equipment, including monitoring instruments, to be financially responsible for specified collection, recycling, treatment and disposal of past and present covered products placed on the market in the European Union. As a manufacturer of covered products, we may be required to register as a producer in some European Union countries, and we may incur some financial responsibility for the collection, recycling, treatment and disposal of both new product sold, and product already sold prior to the WEEE Directive's enforcement date, including the products of other manufacturers where these are replaced by our own products. European Union Directive 2002/95/EC on the Restriction of the use of Hazardous Substances in electrical and electronic equipment, known as the RoHS Directive, restricts the use of certain hazardous substances, including mercury, lead and cadmium in specified covered products; however, the RoHS Directive currently exempts monitoring instruments from its requirements. If the European Commission were to remove this exemption in the future, we would be required to change our manufacturing processes and redesign products regulated under the RoHS Directive in order to be able to continue to offer them for sale within the European Union. For some products, substituting certain components containing regulated hazardous substances may be difficult, costly or result in production delays. We will continue to review the applicability and impact of both directives on the sale of our products within the European Union, and although we cannot currently estimate the extent of such impact, they are likely to result in additional costs and could require us to redesign or change how we manufacture our products, any of which could adversely affect our operating results. Failure to comply with the directives could result in the imposition of fines and penalties, inability to sell covered products in the European Union and loss of revenues.

Compliance with foreign, federal, state and local environmental laws and regulations represents a small part of our present budget. If we fail to comply with any such laws or regulations, however, a government entity may levy a fine on us or require us to take costly measures to ensure compliance. Any such fine or expenditure may adversely affect our development. We are committed to complying with and, to our knowledge, are in compliance with, all governmental regulations. We cannot predict the extent to which future legislation and regulation could cause us to incur additional operating expenses, capital expenditures, or restrictions and delays in the development of our products and properties.

Table of Contents

RISKS RELATING TO OUR INTELLECTUAL PROPERTY

Our proprietary rights may not adequately protect our technologies.

Our commercial success will depend in part on our obtaining and maintaining patent, trade secret, copyright and trademark protection of our technologies in the United States and other jurisdictions as well as successfully enforcing this intellectual property and defending this intellectual property against third-party challenges. We will only be able to protect our technologies from unauthorized use by third parties to the extent that valid and enforceable intellectual property protections, such as patents or trade secrets, cover them. In particular, we place considerable emphasis on obtaining patent and trade secret protection for significant new technologies, products and processes. Furthermore, the degree of future protection of our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. The degree of future protection of our proprietary rights is also uncertain for products that are currently in the early stages of development such as the Trimetasphere® carbon nanomaterials products-because we cannot predict which of these products will ultimately reach the commercial market or whether the commercial versions of these products will incorporate proprietary technologies.

Our patent position is highly uncertain and involves complex legal and factual questions. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. For example:

we or our licensors might not have been the first to make the inventions covered by each of our pending patent applications and issued patents;

we or our licensors might not have been the first to file patent applications for these inventions;

others may independently develop similar or alternative technologies or duplicate any of our technologies;

it is possible that none of our pending patent applications or the pending patent applications of our licensors will result in issued patents;

our issued patents and issued patents of our licensors may not provide a basis for commercially viable technologies, may not provide us with any competitive advantages, or may be challenged and invalidated by third parties; and

we may not develop additional proprietary technologies that are patentable.

Patents may not be issued for any pending or future pending patent applications owned by or licensed to us, and claims allowed under any issued patent or future issued patent owned or licensed by us may not be valid or sufficiently broad to protect our technologies. Moreover, protection of certain of our intellectual property may be unavailable or limited in the United States or in foreign countries, and certain of our products including our Trimetasphere® carbon nanomaterials products-do not have foreign patent protection. Any issued patents owned by or licensed to us now or in the future may be challenged, invalidated, or circumvented, and the rights under such patents may not provide us with competitive advantages. In addition, competitors may design around our technology or develop competing technologies. Intellectual property rights may also be unavailable or limited in some foreign countries, and in the case of certain products no foreign patents were filed or can be filed. This could make it easier for competitors to capture or increase their market share with respect to related technologies. Although we are not currently involved in any legal proceedings related to intellectual property, we could incur substantial costs to bring suits in which we may assert our patent rights against others or defend ourselves in suits brought against us. An unfavorable outcome of any such litigation could have a material adverse effect on our business and results of operations.

We also rely on trade secrets to protect our technology, especially where we believe patent protection is not appropriate or obtainable. However, trade secrets are difficult to protect. We routinely obtain confidentiality agreements and contractual provisions with our collaborators, employees, and consultants to protect our trade secrets and proprietary know-how. These agreements may be breached and or may not have adequate remedies for such breach. While we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors or

Edgar Filing: LUNA INNOVATIONS INC - Form 10-Q

scientific and other advisors, or those of our strategic partners, may unintentionally or willfully disclose our information to competitors. If we were to enforce a claim that a third party had illegally obtained and was using our trade secrets, our enforcement efforts would be expensive and time consuming, and the outcome would be unpredictable. In addition, courts outside the United States are sometimes unwilling to protect trade secrets. Moreover, if our competitors independently develop equivalent knowledge, methods and know-how, it will be more difficult for us to enforce our rights and our business could be harmed.

If we are not able to defend the patent or trade secret protection position of our technologies, then we will not be able to exclude competitors from developing or marketing competing technologies, and we may not generate enough revenues from product sales to justify the cost of development of our technologies and to achieve or maintain profitability.

Table of Contents

We also rely on trademarks to establish a market identity for Luna and Luna products. To maintain the value of our trademarks, we might have to file lawsuits against third parties to prevent them from using trademarks confusingly similar to or dilutive of our registered or unregistered trademarks. Also, we might not obtain registrations for our pending trademark applications, and might have to defend our registered trademark and pending trademark applications from challenge by third parties. Enforcing or defending our registered and unregistered trademarks might result in significant litigation costs and damages, including the inability to continue using certain trademarks.

Third parties may claim that we infringe their intellectual property, and we could suffer significant litigation or licensing expense as a result.

Various U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in our technology areas. Such third parties may claim that we infringe their patents. Because patent applications can take several years to result in a patent issuance, there may be currently pending applications, unknown to us, which may later result in issued patents that our technologies may infringe. For example, we are aware of competitors with patents in technology areas applicable to our optical test equipment products. Such competitors may allege that we infringe these patents. There could also be existing patents of which we are not aware that our technologies may inadvertently infringe. If third parties assert claims against us alleging that we infringe their patents or other intellectual property rights including third parties that have asserted claims against businesses that we have acquired prior to our acquisition of these businesses we could incur substantial costs and diversion of management resources in defending these claims, and the defense of these claims could have a material adverse effect on our business, financial condition, and results of operations. In addition, if third parties assert claims against us and we are unsuccessful in defending against these claims, these third parties may be awarded substantial damages, as well as injunctive or other equitable relief against us, which could effectively block our ability to make, use, sell, distribute, or market our products and services in the United States or abroad.

For example, a former customer, Hansen Medical, Inc, recently filed a lawsuit against us alleging, among other things, misappropriation of trade secrets. The lawsuit makes an unspecified claim for damages, however the plaintiff has not indicated how it will substantiate such damages and we are unable to reasonably estimate the amount of damages, if any, that it will seek. In addition, the plaintiff in the suit may seek equitable relief, including, for example, an injunction to prevent us from misusing the plaintiff's trade secrets or proprietary information or an injunction to prevent us from working with other companies. We believe the allegations are without merit and we intend to vigorously defend ourselves in this lawsuit. We have filed a cross-claim against the plaintiff alleging misappropriation of trade secrets, unfair competition, breach of contract, and breach of the implied covenant of good faith and fair dealing and seeking a declaratory judgment as to the parties rights and obligations. Our cross-claim seeks damages and equitable relief. However, we cannot predict the ultimate outcome of this litigation, and we are unable to estimate any potential liability we may incur.

In another example, we acquired a business that had received a letter in 2002 from a competitor alleging infringement of certain patents. The competitor sent an additional letter on January 14, 2004 to the business that we acquired, again alleging infringement of the competitor's patents. Neither we nor the business that we acquired have received any further communications from this third party. We cannot currently predict whether this third party, or any other third party, will assert a claim against us, or whether any third parties that have asserted such claims against businesses that we have acquired will assert claims or pursue infringement litigation against us; nor can we predict the ultimate outcome of any such potential claims or litigation.

Commercial application of nanotechnologies in particular, or technologies involving nanomaterials, is new and the scope and breadth of patent protection is uncertain. Consequently, the patent positions of companies involved in nanotechnologies have not been tested and complex legal and factual questions for which important legal principles will be developed or may remain unresolved. In addition, it is not clear whether such patents will be subject to interpretations or legal doctrines that differ from conventional patent law principles. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our nanotechnology-related intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our nanotechnology-related patents or in third party patents.

In the event that a claim relating to intellectual property is asserted against us, or third parties not affiliated with us hold pending or issued patents that relate to our products or technology, we may seek licenses to such intellectual property or challenge those patents. However, we may be unable to obtain these licenses on commercially reasonable terms, if at all, and our challenge of the patents may be unsuccessful. Our failure to obtain the necessary licenses or other rights could prevent the sale, manufacture, or distribution of our products and, therefore, could have a material adverse effect on our business, financial condition, and results of operations.

Table of Contents

A substantial portion of our technology is subject to retained rights of our licensors, and we may not be able to prevent the loss of those rights or the grant of similar rights to third parties.

A substantial portion of our technology is licensed from academic institutions, corporations and government agencies. Under these licensing arrangements, a licensor may obtain rights over the technology, including the right to require us to grant a license to one or more third parties selected by the licensor or that we provide licensed technology or material to third parties for non-commercial research. The grant of a license for any of our core technologies to a third party could have a material and adverse effect on our business. In addition, some of our licensors retain certain rights under the licenses, including the right to grant additional licenses to a substantial portion of our core technology to third parties for noncommercial academic and research use. It is difficult to monitor and enforce such noncommercial academic and research uses, and we cannot predict whether the third party licensees would comply with the use restrictions of such licenses. We could incur substantial expenses to enforce our rights against them. We also may not fully control the ability to assert or defend those patents or other intellectual property which we have licensed from other entities, or which we have licensed to other entities.

In addition, some of our licenses with academic institutions give us the right to use certain technology previously developed by researchers at these institutions. In certain cases we also have the right to practice improvements on the licensed technology to the extent they are encompassed by the licensed patents and within our field of use. Our licensors may currently own and may in the future obtain additional patents and patent applications that are necessary for the development, manufacture and commercial sale of our anticipated products. We may be unable to agree with one or more academic institutions from which we have obtained licenses that certain intellectual property developed by researchers at these academic institutions is covered by our existing licenses. In the event that the new intellectual property is not covered by our existing licenses, we would be required to negotiate a new license agreement. We may not be able to reach agreement with current or future licensors on commercially reasonable terms, if at all, or the terms may not permit us to sell our products at a profit after payment of royalties, which could harm our business.

Some of our patents may cover inventions that were conceived or first reduced to practice under, or in connection with, U.S. government contracts or other federal funding agreements. With respect to inventions conceived or first reduced to practice under a federal funding agreement, the U.S. government may retain a nonexclusive, non-transferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the invention throughout the world. We may not be successful in our efforts to retain title in patents, maintain ownership of intellectual property or in limiting the U.S. government's rights in our proprietary technologies and intellectual property whether such intellectual property was developed in the performance of a federal funding agreement or developed at private expense.

RISKS RELATING TO OUR COMMON STOCK

Our common stock price has been volatile and we expect that the price of our common stock will fluctuate substantially in the future.

Before our initial public offering, there was no public market for our common stock, and in the future, an active public trading market may not be sustained. The public trading price for our common stock will continue to be affected by a number of factors, including:

changes in earnings estimates, investors' perceptions, recommendations by securities analysts or our failure to achieve analysts' earnings estimates;

changes in our status as an entity eligible to receive SBIR contracts and grants;

variations in our or our competitors' results of operations or cash flows;

general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors;

announcements by us, or our competitors, of acquisitions, new products, significant contracts, commercial relationships or capital commitments;

commencement of, or involvement in, litigation;

any major change in our board of directors or management;

changes in governmental regulations or in the status of our regulatory approvals;

announcements related to patents issued to us or our competitors and to litigation;

a lack of, limited or negative industry or security analyst coverage; and

developments in our industry.

Table of Contents

In addition, the stock prices of many technology companies have experienced wide fluctuations that have often been unrelated to the operating performance of those companies. These factors may materially and adversely affect the market price of our common stock.

If there are substantial sales of our common stock, our stock price could decline.

If our existing stockholders sell a large number of shares of our common stock or the public market perceives that these sales may occur, the market price of our common stock could decline.

As of June 2, 2006, the date of our initial public offering, employees and former employees holding approximately 1.8 million shares of our common stock or options exercisable for our common stock had entered into an agreement to not sell more than 20.0% of such shares in any year during the five years following the effective date of our initial public offering, provided that if any shares subject to such annual limit are not sold in a given year then such shares may be sold in subsequent years. In addition, certain members of our management holding options exercisable for approximately 2.2 million shares of our common stock had entered into an agreement not to sell more than 15.0% of such shares in any year during the five years following the effective date of such initial public offering. On January 23, 2007, certain members of our management team entered into amended and restated stock sale restriction agreements whereby such officers agreed not to sell more than a fixed number of beneficially held shares of our common stock for a two year period ending December 31, 2008. At the time these agreements were entered into, such officers beneficially owned an aggregate of 5,010,453 shares of our common stock, including vested and unvested options to purchase common stock, which are subject to the sale restriction agreements. We have the right to waive any of these resale restrictions for employees and management at our discretion, and in such instance, the shares would become freely tradable. Upon the expiration or waiver of these resale restrictions, these individuals may sell, or the public market may perceive that these individuals will sell, a large number of shares of our common stock, which may cause the market price of our common stock to decline.

Our financial results may vary significantly from period to period, which may reduce our stock price.

Historically, our financial results have exhibited significant seasonality. For example, we typically have lower product and license revenue in the first half of the year and higher product revenue in the second half of the year. We expect such seasonality to continue. In addition, our financial results may fluctuate as a result of a number of factors, many of which are outside of our control, which may cause the market price of our common stock to fall. For these reasons, comparing our operating results on a period-to-period basis may not be meaningful, and you should not rely on our past results as an indication of our future performance. Our financial results may be negatively affected by any of the risk factors listed in this Risk factors section and, in particular, the following risks:

a reduction of contract research funding;

decisions by government agencies, academic institutions or corporations not to exercise contract options or to modify, curtail or terminate our major contracts;

failure to estimate or control contract costs;

adverse judgments or settlements in legal disputes;

expenses related to acquisitions, mergers or joint ventures; and

other one-time financial charges.

We have incurred and will continue to incur increased costs as a result of being a public company.

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses. We have incurred and will continue to incur costs associated with our public company reporting requirements. We also have incurred and will continue to incur costs

Edgar Filing: LUNA INNOVATIONS INC - Form 10-Q

associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act of 2002, as well as rules implemented by the SEC and the National Association of Securities Dealers, Inc., or NASD. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly. We cannot accurately predict or estimate the amount of additional costs we may incur or the timing of such costs.

If our internal controls over financial reporting are found not to be effective or if we make disclosure of existing or potential significant deficiencies or material weaknesses in those controls, Investors could lose confidence in our financial reports, and our stock price may be adversely affected.

Beginning with our Annual Report for the year ending December 31, 2007, Section 404 of the Sarbanes-Oxley Act of 2002 requires us to include an internal control report with our Annual Report on Form 10-K. That report must include management's assessment of the effectiveness of our internal control over financial reporting as of the end of the fiscal year.

Table of Contents

Additionally, our independent registered public accounting firm will be required to issue a report on management's assessment of our internal control over financial reporting and a report on their evaluation of the operating effectiveness of our internal control over financial reporting beginning with our Annual Report for the year ending December 31, 2008.

We continue to evaluate our existing internal control over financial reporting against the standards adopted by the Public Company Accounting Oversight Board, or PCAOB. During the course of our ongoing evaluation of the internal controls, we may identify areas requiring improvement, and may have to design enhanced processes and controls to address issues identified through this review. Remedying any deficiencies, significant deficiencies or material weaknesses that we or our independent registered public accounting firm may identify, may require us to incur significant costs and expend significant time and management resources. We cannot assure you that any of the measures we implement to remedy any such deficiencies will effectively mitigate or remedy such deficiencies. Investors could lose confidence in our financial reports, and our stock price may be adversely affected, if our internal controls over financial reporting are found not to be effective by management or by an independent registered public accounting firm or if we make disclosure of existing or potential significant deficiencies or material weaknesses in those controls.

Our independent auditors have previously identified material weaknesses and significant deficiencies in our internal controls, and if we are unable to develop, implement and maintain appropriate controls we will not be able to comply with applicable regulatory requirements imposed on reporting companies.

In connection with the audit of our financial statements for the year ended December 31, 2006, our independent registered public accounting firm did not identify any material weaknesses or significant deficiencies in our internal control over financial reporting. Although we do not believe we have material weaknesses or significant deficiencies related to our policies and procedures, we have not performed specific tests to determine the effectiveness of key controls within these policies and procedures. We intend to monitor those policies and procedures in connection with the establishment of a formally documented system of internal control. We are continuing documentation of our internal control processes in order to identify additional areas for improvement as well as in anticipation of our future reporting requirements under the Sarbanes-Oxley Act of 2002.

While we anticipate being able to implement fully the requirements relating to internal control and all other applicable requirements of the Sarbanes-Oxley Act of 2002 in a timely fashion, we cannot be certain as to the timing of the completion of our evaluation and testing and any necessary remediation or the impact of the same on our operations. Our development, implementation and maintenance of appropriate internal controls will depend materially both on our successful hiring and retention of key senior accounting personnel. If we are not able to complete the assessment required under Section 404 in a timely manner, we would be unable to conclude that our internal control over financial reporting is effective as of December 31, 2007.

If we are unable to retain and attract qualified personnel, to implement and integrate financial reporting and accounting systems or if we are unable to scale these systems to our growth, we may not have adequate, accurate or timely financial information, and we may be unable to meet our reporting obligations or comply with the requirements of the SEC, the NASDAQ Global Market or the Sarbanes-Oxley Act of 2002, which could result in the imposition of sanctions, including the suspension or delisting of our common stock from the NASDAQ Global Market and the inability of registered broker dealers to make a market in our common stock, or investigation by regulatory authorities. Any such action or other negative results caused by our inability to meet our reporting requirements or comply with legal and regulatory requirements or by disclosure of an accounting, reporting or control issue could adversely affect the price of our common stock. Further and continued determinations that there are significant deficiencies or material weaknesses in the effectiveness of our internal control over financial reporting could also reduce our ability to obtain financing or could increase the cost of any financing we obtain and require additional expenditures to comply with applicable requirements.

As of September 30, 2007, our directors and management collectively controlled approximately 27% of our outstanding common stock.

As of September 30, 2007, our directors and executive officers and their affiliates collectively controlled approximately 27% of our outstanding common stock. As a result, these stockholders, if they act together, will be able to influence our management and affairs and all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. You and other stockholders will have minimal influence over these actions. This concentration of ownership may have the effect of delaying or preventing a change in control of our company and might adversely affect the market price of our common stock.

Anti-takeover provisions in our amended and restated certificate of incorporation and bylaws and Delaware law could discourage a takeover.

Table of Contents

Our amended and restated certificate of incorporation and bylaws and Delaware law contain provisions that might enable our management to resist a takeover. These provisions include:

a classified board of directors;

advance notice requirements to stockholders for matters to be brought at stockholder meetings;

a supermajority stockholder vote requirement for amending certain provisions of our amended and restated certificate of incorporation and bylaws; and

the right to issue preferred stock without stockholder approval, which could be used to dilute the stock ownership of a potential hostile acquirer.

These provisions might discourage, delay or prevent a change in control of our company or a change in our management. The existence of these provisions could adversely affect the voting power of holders of common stock and limit the price that investors might be willing to pay in the future for shares of our common stock.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

(a) Unregistered Sales of Equity Securities during the Three Months Ended September 30, 2007

During the three months ended September 30, 2007, we issued an aggregate of 13,446 shares of our common stock, \$0.001 par value per share, upon the exercise of certain warrants issued in February 2006 to the former stockholders of Luna Technologies, Inc. Net proceeds from these warrant exercises were approximately \$23,800. We believe these transactions were exempt from registration pursuant to Section 4(2) of the Securities Act of 1933, as amended. No underwriters were engaged by us in connection with such issuances.

(b) Use of Proceeds from Sale of Registered Equity Securities

On June 6, 2006, we completed the initial public offering of our common stock, \$0.001 par value per share, pursuant to our Registration Statement on Form S-1, as amended (File No. 333-131764) that was declared effective on June 2, 2006. We sold 3,500,000 shares in the offering at a price to the public of \$6.00 per share and received net proceeds of \$17.87 million in the offering.

We are using, or expect to use, the net proceeds of the offering principally to fund further development and expansion of our products and product candidates, in particular our nanomaterial and ultrasound-related medical product candidates, and for general working capital purposes. We may also use a portion of the net proceeds for the acquisition of, or investment in, companies, technologies, products or assets that complement our business. We have no present commitments or binding agreements to enter into any acquisitions or investments. Pending these uses, we intend to continue to invest the net proceeds of our initial public offering in short-term, investment-grade interest-bearing securities or guaranteed obligations of the U.S. government.

(c) Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

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

Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Quarterly Report on Form 10-Q to be signed on its behalf by the undersigned thereunto duly authorized.

Date: November 13, 2007

Luna Innovations Incorporated

By:

/s/ DALE E. MESSICK
Dale E. Messick
Chief Financial Officer
(Principal Financial and Accounting Officer
and duly authorized Officer)

34

Table of Contents

EXHIBIT INDEX

Exhibit

Number Description

3.1(1)	Amended and Restated Certificate of Incorporation of the Registrant. (Exhibit 3.2)
3.2(2)	Amended and Restated Bylaws of the Registrant. (Exhibit 3.4)
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

-
- (1) Incorporated by reference to the exhibits to the Registrant's Current Report on Form 8-K dated June 2, 2006 (file No. 000-52008). The number given in parenthesis indicates the corresponding exhibit number in such Form 8-K.
- (2) Incorporated by reference to the exhibits to the Registrant's Registration Statement on Form S-1, as amended, dated June 2, 2006 (file No. 333-131764). The number given in parenthesis indicates the corresponding exhibit number in such Form S-1.