ENTROPIC COMMUNICATIONS INC
Form 10-Q
May 07, 2008
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SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

(Mark One)

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended March 31, 2008

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: 001-33844

ENTROPIC COMMUNICATIONS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**33-0947630**
(State or Other Jurisdiction of Incorporation)	**(IRS Employer Identification No.)**

6290 Sequence Drive

San Diego, CA 92121
(Address of Principal Executive Offices and Zip Code)

(858) 768-3600
(Registrant s Telephone Number, Including Area Code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

x Yes ¨ No

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

Large accelerated filer ¨ Accelerated filer ¨ Non-accelerated filer x Smaller reporting company ¨

(Do not check if a smaller reporting company)

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

As of the close of business on April 30, 2008, 68,755,116 shares of the registrant s common stock, $0.001 par value per share, were outstanding.

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ENTROPIC COMMUNICATIONS, INC.

FORM 10-Q

For the Quarterly Period Ended March 31, 2008

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PART I: FINANCIAL INFORMATION

Item 1. ***Financial Statements***

ENTROPIC COMMUNICATIONS, INC.

UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	March 31, 2008	December 31, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 16,545	$ 51,475
Restricted cash		58
Marketable securities	18,586	2,965
Accounts receivable, net	37,852	24,489
Inventory	14,242	15,332
Prepaid expenses, deferred income taxes and other current assets	2,004	2,238
Total current assets	89,229	96,557
Property and equipment, net	12,027	8,952
Intangible assets, net	32,309	34,145
Goodwill	86,256	86,256
Other long-term assets	389	416
Total assets	$ 220,210	$ 226,326
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 19,053	$ 18,909
Accrued payroll and benefits	4,314	4,253
Deferred revenues	303	303
Current portion of line of credit and loans payable		2,860
Current portion of software licenses and capital lease obligations	268	384
Total current liabilities	23,938	26,709
Stock repurchase liability	1,591	1,765
Lines of credit and loans payable, less current portion		5,547
Other long-term liabilities	3,061	1,907
Commitments and contingencies		
Stockholders equity:		
Preferred stock		
Common stock	69	68
Additional paid-in capital	287,703	282,627
Accumulated deficit	(96,152)	(92,297)
Total stockholders equity	191,620	190,398
Total liabilities, preferred stock and stockholders equity	$ 220,210	$ 226,326

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

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ENTROPIC COMMUNICATIONS, INC.

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

	Three Months Ended March 31,	
	2008	**2007**
Net revenues	$ 41,988	$ 20,026
Cost of net revenues	22,837	14,531
Gross profit	19,151	5,495
Operating expenses:		
Research and development	13,313	4,190
Sales and marketing	4,144	1,500
General and administrative	3,523	767
Amortization of purchased intangibles	596	
Restructuring charge	1,079	
Total operating expenses	22,655	6,457
Loss from operations	(3,504)	(962)
Other expense, net	(198)	(150)
Loss before income taxes	$ (3,702)	$ (1,112)
Provision for income taxes	154	
Net loss	$ (3,856)	$ (1,112)
Accretion of redeemable convertible preferred stock		(32)
Net loss attributable to common stockholders	$ (3,856)	$ (1,144)
Net loss per share attributable to common stockholders basic and diluted	$ (0.06)	$ (0.21)
Weighted average number of shares used to compute loss per share attributable to common stockholders	66,662	5,472

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

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ENTROPIC COMMUNICATIONS, INC.

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Three Months Ended March 31,	
	2008	**2007**
Operating activities:		
Net loss	$ (3,856)	$ (1,112)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	660	323
Amortization of purchased intangible assets	1,836	
Stock-based compensation to consultants	26	25
Stock-based compensation to employees	3,598	115
Interest expense attributable to amortization and early payoff of debt issuance costs	476	
Revaluation of preferred stock warrant liabilities		272
Impairment of assets related to restructuring charge	259	
Loss on disposal of assets	8	
Changes in operating assets and liabilities:		
Accounts receivable	(13,363)	(3,503)
Inventory	1,089	(6,865)
Prepaid expenses and other current assets	234	(187)
Other long-term assets	(64)	(49)
Accounts payable and accrued expenses	144	4,647
Accrued payroll and benefits	62	(118)
Deferred revenues		192
Other long-term liabilities	1,154	
Net cash used in operating activities	(7,737)	(6,260)
Investing activities:		
Purchases of property and equipment	(3,938)	(248)
Purchases of marketable securities	(17,120)	
Sales/maturities of marketable securities	1,500	5,111
Net cash (used in) provided by investing activities	(19,558)	4,863
Financing activities:		
Principal payments on software license and capital lease obligations	(116)	(189)
Principal payments on debt obligations	(8,856)	
Net proceeds from the issuance of common stock	1,448	548
Payment of equity issuance costs	(75)	
Repurchase of restricted stock	(94)	
Net cash (used in) provided by financing activities	(7,693)	359
Net decrease in cash and cash equivalents	(34,988)	(1,038)
Cash and cash equivalents at beginning of period	51,533	5,928
Cash and cash equivalents at end of period	$ 16,545	$ 4,890

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

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ENTROPIC COMMUNICATIONS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2008

1. Organization and Summary of Significant Accounting Policies

Business

Entropic Communications, Inc. (the Company) was organized under the laws of the state of Delaware on January 31, 2001. The Company is a fabless semiconductor company that designs, develops and markets systems solutions to enable connected home entertainment.

In October 2007, the Company completed a 1-for-3.25 reverse stock split. The accompanying financial statements and notes to the financial statements give retroactive effect to the reverse stock split for all periods presented.

Basis of Presentation

The accompanying interim unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (GAAP) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X promulgated by the Securities and Exchange Commission (SEC). They do not include all of the information and footnotes required by GAAP for complete financial statements. These financial statements should be read in conjunction with the Company s audited consolidated financial statements and notes thereto as of and for the year ended December 31, 2007 included in the Company s Annual Report on Form 10-K (Annual Report) filed on March 3, 2008 with the SEC.

The interim condensed consolidated financial statements included herein are unaudited; however, they contain all normal recurring accruals and adjustments that, in the opinion of management, are necessary to present fairly the Company s consolidated financial position, results of operations and cash flows as of and for the periods indicated. The interim results are not necessarily indicative of the results to be expected for future quarters or the full year.

The accompanying unaudited condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All inter-company accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Among the significant estimates affecting the condensed consolidated financial statements are those related to business combinations, revenue recognition, allowance for doubtful accounts, inventory reserves, long-lived assets (including goodwill and intangible assets), warranty reserves, valuation of warrants, valuation of equity securities and stock-based compensation. On an on-going basis, management reviews its estimates based upon currently available information. Actual results could differ materially from those estimates.

Revenue Recognition

The Company s revenues are generated principally by sales of its semiconductor products. During the three months ended March 31, 2008 and 2007, product revenues represented 98% and 100%, respectively, of its total net revenues. The Company also generates service revenues from development contracts.

The majority of the Company s sales occur through the efforts of its direct sales force. The remainder of the Company s sales occurs through distributors. During the three months ended March 31, 2008 and 2007, more than 99% of the Company s sales occurred through the efforts of its direct sales force.

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In accordance with SEC Staff Accounting Bulletin (SAB) No. 101, *Revenue Recognition in Financial Statements*, and SAB No. 104, *Revenue Recognition*, the Company recognizes product revenues when the following fundamental criteria are met: (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred or services have been rendered, (iii) the price to the customer is fixed or determinable and (iv) collection of the resulting receivable is reasonably assured. These criteria are usually met at the time of product shipment. However, the Company does not recognize revenue until all customer acceptance requirements have been met, when applicable.

A portion of the Company s sales are made through distributors under agreements allowing for pricing credits and/or rights of return. Product revenues on sales made through these distributors are not recognized until the distributors ship the product to their customers. The Company records reductions to revenues for estimated product returns and pricing adjustments, such as competitive pricing programs, in the same period that the related revenue is recorded. To date, product returns and pricing adjustments have not been significant.

The Company also has entered into an inventory hubbing arrangement with a key customer. Pursuant to this arrangement, the Company delivers products to the designated third party warehouse based upon the customer s projected needs, but does not recognize product revenue unless and until the customer removes the Company s products from the third party warehouse to incorporate into its own products.

The Company derives revenues from development contracts that involve new and unproven technologies. Revenues under these contracts are deferred until customer acceptance is obtained, and other contract-specific terms have been completed in accordance with the completed contract method of American Institute of Certified Public Accountants Statement of Position 81-1, *Accounting for Performance of Construction-Type and Certain Production-Type Contracts*. Provisions for losses related to development contracts, if any, are recognized in the period in which the loss first becomes probable and reasonably estimable. The costs associated with development contracts are included in cost of service revenue. The Company defers the cost of services provided under its development contracts.

The Company acquired a development agreement in connection with the acquisition of RF Magic, Inc. (RF Magic) that provides the Company with royalties in exchange for an exclusive right to manufacture and sell certain products. The Company has determined that it is not able to reliably estimate the royalties earned in the period the sales occur. Thus, the Company records revenues based on cash receipts. The royalty revenue recorded during the three months ended March 31, 2008 and 2007 were $966,000 and $0, respectively.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist primarily of cash and cash equivalents, marketable securities, accounts receivable, leases payable and lines of credit and loans payable. The Company s policy is to place its cash and cash equivalents with high quality financial institutions in order to limit its credit exposure. Credit is extended based on an evaluation of the customer s financial condition and a cash deposit is generally not required. The Company estimates potential losses on trade receivables on an ongoing basis.

The Company invests cash in deposits and money market funds with major financial institutions, U.S. government obligations, debt securities of corporations with strong credit ratings and a variety of industries. It is the Company s policy to invest in instruments that have a final maturity of no longer than two years, with a portfolio weighted average maturity of no longer than 12 months.

Inventories

Inventories are stated at the lower of cost (first-in, first-out) or market. Lower of cost or market adjustments reduce the carrying value of the related inventory and take into consideration reductions in sales prices, excess inventory levels and obsolete inventory. These adjustments are done on a part-by-part basis. Once established, these adjustments are considered permanent and are not reversed until the related inventory is sold or disposed.

Guarantees and Indemnifications

In the ordinary course of business, the Company has entered into agreements with customers that include indemnity provisions. To date, there have been no known events or circumstances that have resulted in any significant costs related to these indemnification provisions, and as a result, no liabilities have been recorded in the accompanying interim unaudited financial statements.

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Rebates

The Company accounts for rebates in accordance with Emerging Issues Task Force (EITF) Issue No. 01-9, *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor s Products)*, and, accordingly, at the time of the sale accrues 100% of the potential rebate as a reduction to revenue and does not apply a breakage factor. The amount of these reductions is based upon the terms included in various rebate agreements. The Company reverses the accrual for unclaimed rebates amounts as specific rebate programs contractually end or when management believes unclaimed rebates are no longer subject to payment and will not be paid.

Warranty Accrual

The Company s products are subject to warranty periods of one year or more. The Company provides for the estimated future costs of replacement upon shipment of the product as cost of net revenues. The Company has not incurred significant warranty claims to date. The warranty accrual is based on management s best estimate of expected costs associated with product failure and historical product failures.

Research and Development Costs

Research and development costs are expensed as incurred and primarily include costs related to personnel, outside services (which consist primarily of contract labor services), fabrication masks, architecture licenses, engineering design development software and hardware tools, allocated overhead expenses and depreciation of equipment used in research and development.

Income Taxes

The Company utilizes the liability method of accounting for income taxes as set forth in Statement of Financial Accounting Standards (SFAS) No. 109, *Accounting for Income Taxes* (SFAS 109). Under the liability method, deferred taxes are determined based on the temporary differences between the financial statement and tax basis of assets and liabilities using tax rates expected to be in effect during the years in which the basis differences reverse. A valuation allowance is recorded when it is more likely than not that some of the deferred tax assets will not be realized.

The Company also follows Financial Accounting Standards Board (FASB) issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes An Interpretation of FASB Statement No. 109* (FIN 48) which provides detailed guidance for the financial statement recognition, measurement and disclosure of uncertain tax positions recognized in an enterprise s financial statements in accordance with SFAS 109. Income tax positions must meet a more-likely-than-not recognition threshold at the effective date to be recognized upon the adoption of FIN 48 and in subsequent periods. The Company recognizes potential accrued interest and penalties related to unrecognized tax benefits within operations as income tax expense.

Stock-Based Compensation

Effective January 1, 2006, the Company adopted the provisions of SFAS No. 123 (revised 2004), *Share-Based Payment* (SFAS 123R), including the provisions of SAB No. 107 (SAB 107) and SAB No. 110 (SAB 110). Under SFAS 123R, stock-based compensation cost is measured at the grant date, based on the estimated fair value of the award, and is recognized as expense over the employee s requisite service period. The Company has not granted awards with vesting subject to market conditions. The Company adopted the provisions of SFAS 123R using the prospective transition method. Accordingly, prior periods have not been revised for comparative purposes.

The valuation provisions of SFAS 123R apply to new awards and to awards that are outstanding on the effective date, January 1, 2006, which are subsequently modified or canceled. Prior to the adoption of SFAS 123R, the Company used the intrinsic value method prescribed by Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25), related interpretations, and the disclosure-only provisions of SFAS No. 123, *Accounting for Stock-Based Compensation* for employee stock options and recorded compensation cost for options granted at exercise prices that were less than market value of the Company s common stock at the date of grant. Pursuant to SFAS 123R, as the Company utilized the minimum value method through December 31, 2005, the Company will continue to recognize compensation expense relating to unvested awards as of the date of adoption using APB 25 which is the same accounting principle originally applied to those awards.

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The stock-based compensation for the Company s 2007 Employee Stock Purchase Plan (ESPP) was determined using the Black-Scholes option pricing model and the provisions of FASB Technical Bulletin No. 97-1, *Accounting under Statement 123 for Certain Employee Stock Purchase Plans with a Look-Back Option*, as amended by SFAS 123R.

The Company accounts for stock-based compensation awards granted to non-employees in accordance with EITF Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services* (EITF 96-18). Under EITF 96-18, the Company determines the fair value of the stock-based compensation awards granted as either the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable. If the fair value of the equity instruments issued is used, it is measured using the stock price and other measurement assumptions as of the earlier of either (1) the date at which a commitment for performance by the counterparty to earn the equity instruments is reached, or (2) the date at which the counterparty s performance is complete.

Due to the adoption of SFAS 123R, the Company recognizes excess tax benefits associated with stock-based compensation to stockholders equity only when realized. When assessing whether excess tax benefits relating to stock-based compensation have been realized, the Company follows the with and without approach excluding any indirect effects to be realized until after the utilization of all other tax benefits available to the Company.

Segment Reporting

SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information* (SFAS 131), establishes standards for the way public business enterprises report information about operating segments in annual consolidated financial statements and requires that those enterprises report selected information about operating segments in interim financial reports. SFAS 131 also establishes standards for related disclosures about products and services, geographic areas and major customers.

Operating segments are defined as components of an enterprise for which separate financial information is available and evaluated regularly by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company is organized as, and operates in, one reportable segment: the design, development and sale of silicon integrated circuits. Products within this segment are embedded in electronic devices used to enable the delivery of multiple streams of HD video and other multimedia content for entertainment purposes into and throughout the home. The Company s chief operating decision maker is its Chief Executive Officer (CEO). The CEO reviews financial information presented on a consolidated basis evaluating financial performance and allocating resources. There are no segment managers who are held accountable for operations below the consolidated financial statement level. The Company s assets are primarily located in the United States of America and not allocated to any specific region. Therefore, geographic information is presented only for total revenue.

Recently Issued Accounting Standards

In September 2006, FASB issued SFAS No. 157, *Fair Value Measurements* (SFAS 157), which defines fair value, establishes a framework for measuring fair value under GAAP and expands disclosures about fair value measurements. SFAS 157 does not require any new fair value measurements but rather eliminates inconsistencies in guidance found in various prior accounting pronouncements. The Company adopted this pronouncement as of January 1, 2008 for financial instruments. Although the adoption of SFAS 157 did not have an impact on its interim financial results, the Company is now required to provide additional disclosures as part of its financial statements. See Note 2 for information and related disclosures regarding the Company s fair value measurements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*, which permits entities to choose to measure eligible financial instruments and certain other items at fair value that are not currently required to be measured at fair value. Unrealized gains and losses on items for which the fair value option have been elected are reported in earnings at each subsequent reporting date. The Company adopted this pronouncement in the first quarter of 2008 and it did not have an impact on its interim financial results.

In June 2007, the FASB ratified EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* (EITF 07-3). EITF 07-3 requires non-refundable advance payments for goods and services to be used in future research and development activities to be recorded as an asset and the payments to be expensed when the research and development activities are performed. The Company adopted this standard in the first quarter of 2008 and it did not have an impact on its interim financial results.

In December 2007, the FASB issued SFAS No. 141R, *Business Combinations* (SFAS 141R). SFAS 141R establishes principles and requirements for how the acquirer of a business recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree. The statement also provides guidance for recognizing and measuring the goodwill acquired in the business combination and determines what information to disclose to enable users of the financial statement to evaluate the nature and financial effects of the business combination. SFAS 141R is effective for financial statements issued for fiscal years beginning after December 15, 2008. Accordingly, any business combinations the Company engages in will be recorded and disclosed following existing GAAP until January 1, 2009. The Company expects SFAS 141R will have an impact on its consolidated financial statements when effective, but the nature and magnitude of the specific effects will depend upon the nature, terms and size of the acquisitions consummated after the effective date. The Company is still assessing the impact of this standard on its future consolidated financial statements.

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2. Supplemental Financial Information

Fair Value of Financial Instruments

The Company held certain financial assets, including cash equivalents and marketable securities that are required to be measured at fair value on a recurring basis. Cash equivalents include commercial paper and corporate bonds of high credit quality. Marketable securities were carried at amortized cost which approximated fair value.

SFAS 157 establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include: Level 1, defined as observable inputs such as quoted prices in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions.

The fair value of the Company s financial assets subject to the disclosure requirements of SFAS 157 was determined using the following levels of inputs as of March 31, 2008 (in thousands):

	Fair Value Measurements as of March 31, 2008		
	Total	Level 1	Level 2

- the high cost of clinical trials and our lack of financial and other resources; and
- our inability to partner with firms with sufficient resources to assist us in conducting clinical trials.

Success in early clinical trials often is not replicated in later studies, and few research and development projects result in commercial products. At any point, we may abandon development of a product candidate or we may be required to expend considerable resources repeating clinical trials, which would eliminate or adversely impact the timing for revenues from those product candidates. If a clinical study fails to demonstrate the safety and effectiveness of our product candidates, we may abandon the development of the product or product feature that was the subject of the clinical trial, which could harm our business.

Even if we develop products for commercial use, these products may not be accepted by the medical and pharmaceutical marketplaces or be capable of being offered at prices

that will enable us to become profitable. We cannot assure you that our products will be approved by regulatory authorities or ultimately prove to be useful for commercial markets, meet applicable regulatory standards, or be successfully marketed.

We must maintain and expand expensive finance and accounting systems, procedures and controls in order to grow our business and organization, which will increase our costs and require additional management resources.

We completed our initial public offering, or IPO, in October 2007. As a public reporting company, we are required to comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC and Canadian securities regulatory authorities, including expanded disclosure and accelerated reporting requirements and more complex accounting rules. We are also required to comply with marketplace rules and the heightened corporate governance standards of the NYSE Amex. Compliance with these rules has been expensive, and there are additional rules with which we have not yet needed to comply but which we will need to comply with in the future. For example, for this Form 10-K we are not required to have our independent auditors audit our internal control over financial reporting, but next year we will be required to do so. If our independent registered public accounting firm is unable to provide us with an unqualified report as to the effectiveness of our internal control over financial reporting as of the date of our Annual Report on Form 10-K for 2009, or our business grows and we are not able to comply with accelerated reporting obligations, our ability to obtain additional financing

could be impaired. In addition, investors could lose confidence in the reliability of our internal control over financial reporting and in the accuracy of our periodic reports filed with the SEC and with Canadian securities regulatory authorities. A lack of investor confidence in the reliability and accuracy of our public reporting could cause our stock price to decline.

If we do not maintain our current research collaborations with Alcon and Galderma, and enter into additional collaborations, a portion of our funding may decrease and inhibit our ability to develop new products.

We have entered into a collaborative arrangement with Alcon, and we rely on Alcon for joint intellectual property creation and for substantially all of our near-term revenues. Under the agreement, we licensed to Alcon the exclusive rights (except for certain retained marketing rights) to develop, manufacture and commercialize products incorporating the Aganocide compounds for application in connection with the eye, ear and sinus and for use in contact lens solutions. We also recently entered into an agreement with Galderma S.A. to develop and commercialize our Aganocide® compounds, which covers acne and impetigo and potentially other major dermatological conditions, excluding onychomycosis (nail fungus) and orphan drug indications.

We cannot assure you that our collaborations with Alcon or Galderma or any other collaborative arrangement will be successful, or that we will receive the full amount of research funding, milestone payments or royalties, or that any commercially valuable intellectual property will

be created, from these arrangements. If Alcon or Galderma were to breach or terminate its agreement with us or otherwise fail to conduct its collaborative activities successfully and in a timely manner, the research contemplated by our collaboration with them could be delayed or terminated and our costs of performing studies may increase. We plan on entering into additional collaborations and licensing arrangements. We may not be able to negotiate additional collaborations on acceptable terms, if at all, and these collaborations may not be successful. Our current and future success depends in part on our ability to enter into successful collaboration arrangements and maintain the collaboration arrangement we currently have. If we are unable to enter into, maintain or extend successful collaborations, our business may be harmed.

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Our long-term success depends upon the successful development and commercialization of other products from our research and development activities

Our long-term viability and growth will depend upon the successful development and commercialization of other products from our research and development activities. Product development and commercialization is very expensive and involves a high degree of risk. Only a small number of research and development programs result in the commercialization of a product. Success in early stage clinical trials or preclinical work does not ensure that later stage or larger scale clinical trials will be successful. Even if later stage clinical trials are successful, the risk remains that unexpected concerns may arise from additional data or analysis or that obstacles may arise or issues may be identified in connection with review of clinical data with regulatory authorities or that regulatory authorities may disagree with our view of the data or require additional data or information or additional studies.

Conducting clinical trials is a complex, time-consuming and expensive process. Our ability to complete our clinical trials in a timely fashion depends in large part on a number of key factors including protocol design, regulatory and institutional review board approval, the rate of patient enrollment in clinical trials, and compliance with extensive current good clinical practice requirements. We are in many cases using the services of third-party contract clinical trial providers. If we fail to adequately manage the

design, execution and regulatory aspects of our clinical trials, our studies and ultimately our regulatory approvals may be delayed or we may fail to gain approval for our product candidates altogether.

If we do not successfully execute our growth initiatives through the acquisition, partnering and in-licensing of products, technologies or companies, our future performance could be adversely affected.

In addition to the expansion of our pipeline through spending on internal development projects, we anticipate growing through external growth opportunities, which include the acquisition, partnering and in-licensing of products, technologies and companies or the entry into strategic alliances and collaborations. If we are unable to complete or manage these external growth opportunities successfully, we may not be able to grow our business in the way that we currently expect. The availability of high quality opportunities is limited and we are not certain that we will be able to identify suitable candidates or complete transactions on terms that are acceptable to us. In order to pursue such opportunities, we may require significant additional financing, which may not be available to us on favorable terms, if at all. The availability of such financing is limited by the recent tightening of the global credit markets.

We may acquire other businesses or form joint ventures or in-license compounds that could disrupt our business, harm our operating results, dilute your ownership interest in us, or cause us to incur debt or significant expense.

As part of our business strategy, we may pursue acquisitions of complementary businesses and assets, and enter into technology or pharmaceutical compound licensing arrangements. We also may pursue strategic alliances that leverage our core technology and industry experience to enhance our ability to commercialize our product candidates and expand our product offerings or distribution. We have no experience with respect to acquiring other companies and limited experience with respect to the formation of commercial partnering agreements, strategic alliances, joint ventures or in-licensing of compounds. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. If we in-license any additional compounds, we may fail to develop the product candidates, and spend significant resources before determining whether a compound we have in-licensed will produce revenues. Any future acquisitions or in-licensing by us also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could harm our operating results. Integration of an acquired company also may require management resources that otherwise would be available for ongoing development of our existing business. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance or joint venture.

To finance any acquisitions, we may choose to issue shares of our common stock as

consideration, which would dilute your interest in us. If the price of our common stock is low or volatile, we may not be able to acquire other companies for stock. Alternatively, it may be necessary for us to raise additional funds for acquisitions by incurring indebtedness. Additional funds may not be available on terms that are favorable to us, or at all.

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We do not have our own manufacturing capacity, and we plan to rely on partnering arrangements or third-party manufacturers for the manufacture of our potential products.

We do not currently operate manufacturing facilities for clinical or commercial production of our product NeutroPhase and other product candidates. We have no experience in drug formulation or manufacturing, and we lack the resources and the capabilities to manufacture NeutroPhase or any of our product candidates on a clinical or commercial scale. As a result, we have partnered and expect to partner with third parties to manufacture our products or rely on contract manufacturers to supply, store and distribute product supplies for our clinical trials. Any performance failure on the part of our commercial partners or future manufacturers could delay clinical development or regulatory approval of our product candidates or commercialization of our products, producing additional losses and reducing the potential for product revenues.

Our products, if developed and commercialized, will require precise, high quality manufacturing. The failure to achieve and maintain high manufacturing standards, including the incidence of manufacturing errors, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously harm our business. Contract manufacturers and partners often encounter difficulties involving production yields, quality control and quality assurance, as well as shortages of qualified

personnel. These manufacturers and partners are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with current Good Manufacturing Practice and other applicable government regulations and corresponding foreign standards; however, we do not have control over third-party compliance with these regulations and standards. If any of our manufacturers or partners fails to maintain compliance, the production of our products could be interrupted, resulting in delays, additional costs and potentially lost revenues.

In addition, if the FDA or other regulatory agencies approve any of our product candidates for commercial sale, we will need to manufacture them in larger quantities. Significant scale-up of manufacturing will require validation studies, which the FDA must review and approve. If we are unable to successfully increase the manufacturing capacity for a product, the regulatory approval or commercial launch of any drugs may be delayed or there may be a shortage in supply and our business may be harmed as a result.

We depend on skilled and experienced personnel to operate our business effectively. If we are unable to recruit, hire and retain these employees, our ability to manage and expand our business will be harmed, which would impair our future revenue and profitability.

Our success largely depends on the skills, experience and efforts of our officers, especially our Chief Executive Officer, Chief Financial Officer, Vice President of Research and Development, Vice President of Medical Affairs, and other key

employees. The efforts of each of these persons is critical to us as we continue to develop our technologies and as we attempt to transition into a company with commercial products. Any of our officers and other key employees may terminate their employment at any time. The loss of any of our senior management team members could weaken our management expertise and harm our ability to compete effectively, develop our technologies and implement our business strategies.

Our ability to retain our skilled labor force and our success in attracting and hiring new skilled employees will be a critical factor in determining whether we will be successful in the future. Our research and development programs and collaborations depend on our ability to attract and retain highly skilled scientists and technicians. We may not be able to attract or retain qualified scientists and technicians in the future due to the intense competition for qualified personnel among life science businesses, particularly in the San Francisco Bay Area. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific personnel. We have also encountered difficulties in recruiting qualified personnel from outside the San Francisco Bay Area, due to the high housing costs in the area.

If we fail to manage our growth effectively, we may be unable to execute our business plan.

Our future growth, if any, may cause a significant strain on our management, and our operational, financial and other resources. Our ability to manage our growth

effectively will require us to implement and improve our operational, financial and management information systems and to expand, train, manage and motivate our employees. These demands may require the hiring of additional management personnel and the development of additional expertise by management. Any increase in resources devoted to research and product development without a corresponding increase in our operational, financial and management information systems could have a material adverse effect on our business, financial condition, and results of operations.

If our facilities become inoperable, we will be unable to perform our research and development activities, fulfill the requirements under our collaboration agreement and continue developing products and, as a result, our business will be harmed.

We do not have redundant laboratory facilities. We perform substantially all of our research, development and testing in our laboratory located in Emeryville, California. Emeryville is situated on or near active earthquake fault lines. Our facility and the equipment we use to perform our research, development and testing would be costly to replace and could require substantial lead time to repair or replace. The facility may be harmed or rendered inoperable by natural or man-made disasters, including earthquakes, flooding and power outages, which may render it difficult or impossible for us to perform our research, development and testing for some period of time. The inability to perform our research and development activities may result in the loss of partners or harm our

reputation, and we may be unable to regain those partnerships in the future. Our insurance coverage for damage to our property and the disruption of our business may not be sufficient to cover all of our potential losses, including the loss of time as well as the costs of lost opportunities, and may not continue to be available to us on acceptable terms, or at all.

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Obtaining regulatory approval in the United States does not ensure we will obtain regulatory approval in other countries.

We will aim to obtain regulatory approval in the United States as well as in other countries. To obtain regulatory approval to market our proposed products outside of the United States, we and any collaborator must comply with numerous and varying regulatory requirements in other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ significantly from that required to obtain FDA approval. The regulatory approval process in other countries include all of the risk associated with FDA approval as well as additional, presently unanticipated risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects associated with regulatory approval in the United States, including the risk that our product candidates may not be approved for all indications requested and that such approval may be subject to limitations on the indicated uses for which the product may be marketed. In addition, failure to comply with applicable regulatory requirements in other countries can result in, among other things, warning letters, fines,

injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal of the government to renew marketing applications and criminal prosecution.

If we are unable to design, conduct and complete clinical trials successfully, we will not be able to obtain regulatory approval for our products.

In order to obtain FDA approval for our drug product candidates, we must submit to the FDA a New Drug Application, or NDA, demonstrating that the product candidate is safe and effective for its intended use. This demonstration requires significant research and animal tests, which are referred to as preclinical studies, as well as human tests, which are referred to as clinical trials.

Any clinical trials we conduct or that are conducted by our partners may not demonstrate the safety or efficacy of our product candidates. Success in pre-clinical testing and early clinical trials does not ensure that later clinical trials will be successful. Results of later clinical trials may not replicate the results of prior clinical trials and pre-clinical testing. Even if the results of one or more of our clinical trials are positive, we may have to commit substantial time and additional resources to conducting further preclinical studies or clinical trials before we can submit NDAs or obtain FDA approvals for our product candidates, and positive results of a clinical trial may not be replicated in subsequent trials.

Clinical trials are very expensive and difficult to design and implement. The clinical trial process is also time-consuming. Furthermore, if participating patients in

clinical studies suffer drug-related adverse reactions during the course of such trials, or if we or the FDA believe that participating patients are being exposed to unacceptable health risks, we will have to suspend or terminate our clinical trials. Failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon clinical trials or to repeat clinical studies.

In addition, the completion of clinical trials can be delayed by numerous factors, including:

- delays in identifying and agreeing on acceptable terms with prospective clinical trial sites;
- slower than expected rates of patient recruitment and enrollment;
- increases in time required to complete monitoring of patients during or after participation in a trial; and
- unexpected need for additional patient-related data.

Any of these delays, if significant, could impact the timing, approval and commercialization of our product candidates and could significantly increase our overall costs of drug development.

Even if our clinical trials are completed as planned, their results may not support our expectations or intended marketing claims. The clinical trials process may fail to demonstrate that our products are safe and effective for indicated uses. Such failure would cause us to abandon a product candidate for some indications and could delay development of other product candidates.

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Government agencies may establish usage guidelines that directly apply to our proposed products or change legislation or regulations to which we are subject.

Government usage guidelines typically address matters such as usage and dose, among other factors. Application of these guidelines could limit the use of products that we may develop. In addition there can be no assurance that government regulations applicable to our proposed products or the interpretation thereof will not change and thereby prevent the marketing of some or all of our products for a period of time or permanently. The FDA's policies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or in other countries.

Our product candidates may be classified as a drug or a medical device, depending on the mechanism of action, indication for use and prior precedent, and a change in the classification may have an adverse impact on our revenues or our ability to obtain necessary regulatory approvals.

Several potential indications for our product candidates may be regulated under the medical device regulations of the FDA administered by the Center for Devices and Radiological Health and the same physical product may be regulated by the FDA's Center for Drug Evaluation and Research for another indication. Our products

may be classified by the FDA as a drug or a medical device depending upon their mechanism of action, indications for use or claims. For example, for NVC-422, if the indication is for bladder lavage, we believe it would be classified as a medical device, whereas we believe it would be considered a drug when it is indicated for the prevention of urinary tract infection. Similarly, the use of NVC-101 as a solution for cleansing and debriding wounds is considered a medical device. The determination as to whether a particular indication is considered a drug or a device is based in part upon prior precedent. A reclassification by the FDA of an indication from a device to a drug indication during our development for that indication could have a significant adverse impact due to the more rigorous approval process required for drugs, as compared to medical devices. Such a change in classification can significantly increase development costs and prolong the time for development and approval, thus delaying revenues. A reclassification of an indication after approval from a drug to a device could result in a change in classification for reimbursement. In many cases, reimbursement for devices is significantly lower than for drugs and there could be a significant negative impact on our revenues.

We and our collaborators are and will be subject to ongoing FDA obligations and continued regulatory review, such as continued safety reporting requirements, and we and our collaborators may also be subject to additional FDA post-marketing obligations or new regulations, all of which may result in significant expense and which may limit our ability to

commercialize our medical device and drug products candidates.

Any regulatory approvals that we receive may also be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for potentially costly post-marketing follow-up studies. The FDA may require us to commit to perform lengthy Phase IV post-approval studies (as further described below), for which we would have to expend additional resources, which could have an adverse effect on our operating results and financial condition. In addition, if the FDA approves any of our drug product candidates, the labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping for the drug will be subject to extensive regulatory requirements. The subsequent discovery of previously unknown problems with the drugs, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the drugs or the withdrawal of the drugs from the market. If we are not able to maintain regulatory compliance, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution. Any of these events could prevent us from marketing any products we may develop and our business could suffer.

Conducting clinical trials of our product candidates may expose us to expensive liability claims, and we may not be able to maintain liability insurance on reasonable terms or at all.

The risk of clinical trial liability is inherent in the

testing of pharmaceutical and medical device products. If we cannot successfully defend ourselves against any clinical trial claims, we may incur substantial liabilities or be required to limit or terminate testing of one or more of our product candidates. Our inability to obtain sufficient clinical trial insurance at an acceptable cost to protect us against potential clinical trial claims could prevent or inhibit the commercialization of our product candidates. Our current clinical trial insurance covers individual and aggregate claims up to $3 million. This insurance may not cover all claims and we may not be able to obtain additional insurance coverage at a reasonable cost, if at all, in the future. In addition, if our agreements with any future corporate collaborators entitle us to indemnification against product liability losses and clinical trial liability, such indemnification may not be available or adequate should any claim arise.

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If we use biological and hazardous materials in a manner that causes injury, we could be liable for damages. Compliance with environmental regulations can be expensive, and noncompliance with these regulations may result in adverse publicity and potentially significant monetary damages and fines.

Our activities currently require the controlled use of potentially harmful biological materials and other hazardous materials and chemicals and may in the future require the use of radioactive compounds. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. Additionally, we are subject, on an ongoing basis, to U.S. federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations might be significant and could negatively affect our operating results. In addition, if more stringent laws and regulations are adopted in the future, the costs of compliance with these new laws and regulations could be substantial or could impose significant changes in our testing and production process.

The pharmaceutical and biopharmaceutical industries are characterized by patent litigation and any litigation or claim against us may cause us to incur

substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our business and harm our reputation.

There has been substantial litigation in the pharmaceutical and biopharmaceutical industries with respect to the manufacture, use and sale of new products that are the subject of conflicting patent rights. For the most part, these lawsuits relate to the validity, enforceability and infringement of patents. Generic companies are encouraged to challenge the patents of pharmaceutical products in the United States because a successful challenger can obtain nine months of exclusivity as a generic product under the Waxman-Hatch Act. We expect that we will rely upon patents, trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position and we may initiate claims to defend our intellectual property rights as a result. Other parties may have issued patents or be issued patents that may prevent the sale of our products or know-how or require us to license such patents and pay significant fees or royalties in order to produce our products. In addition, future patents may issue to third parties which our technology may infringe. Because patent applications can take many years to issue, there may be applications now pending of which we are unaware that may later result in issued patents that our products may infringe.

Intellectual property litigation, regardless of outcome, is expensive and time-consuming, could divert management’s attention from our business and have a material negative effect on our

business, operating results or financial condition. If such a dispute were to be resolved against us, we may be required to pay substantial damages, including treble damages and attorneys fees if we were to be found to have willfully infringed a third party's patent, to the party claiming infringement, develop non-infringing technology, stop selling any products we develop, cease using technology that contains the allegedly infringing intellectual property or enter into royalty or license agreements that may not be available on acceptable or commercially practical terms, if at all. Our failure to develop non-infringing technologies or license the proprietary rights on a timely basis could harm our business. Modification of any products we develop or development of new products thereafter could require us to conduct additional clinical trials and to revise our filings with the FDA and other regulatory bodies, which would be time-consuming and expensive. In addition, parties making infringement claims may be able to obtain an injunction that would prevent us from selling any products we develop, which could harm our business.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Some of our employees may have been previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise

used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we fail in defending such claims, in addition to paying money damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper or prevent our ability to commercialize product candidates, which could severely harm our business.

If product liability lawsuits are brought against us, they could result in costly litigation and significant liabilities.

The product candidates we are developing or attempting to develop will, in most cases, undergo extensive clinical testing and will require approval from the applicable regulatory authorities prior to sale. However, despite all reasonable efforts to ensure safety, it is possible that we or our collaborators will sell products which are defective, to which patients react in an unexpected manner, or which are alleged to have side effects. The manufacture and sale of such products may expose us to potential liability, and the industries in which our products are likely to be sold have been subject to significant product liability litigation. Any claims, with or without merit, could result in costly litigation, reduced sales, significant liabilities and diversion of our management's time and attention and could have a material adverse effect on our financial condition, business and results of operations.

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If a product liability claim is brought against us, we may be required to pay legal and other expenses to defend the claim and, if the claim is successful, damage awards may not be covered, in whole or in part, by our insurance. We may not have sufficient capital resources to pay a judgment, in which case our creditors could levy against our assets. We may also be obligated to indemnify our collaborators and make payments to other parties with respect to product liability damages and claims. Defending any product liability claims, or indemnifying others against those claims, could require us to expend significant financial and managerial resources.

Failure to obtain sufficient quantities of products and substances necessary for research and development, pre-clinical trials, human clinical trials and product commercialization that are of acceptable quality at reasonable prices or at all could constrain our product development and have a material adverse effect on our business.

We have relied and will continue to rely on contract manufacturers for the foreseeable future to produce quantities of products and substances necessary for research and development, pre-clinical trials, human clinical trials and product commercialization. It will be important to us that such products and substances can be manufactured at a cost and in quantities necessary to make them commercially viable. At this point in time, we have not attempted to identify, and do not know whether there will be, any third party manufacturers which will be able to meet our needs with respect to timing, quantity and quality for

commercial production. In addition, if we are unable to contract for a sufficient supply or required products and substances on acceptable terms, or if we should encounter delays or difficulties in our relationships with manufacturers, our research and development, pre-clinical and clinical testing would be delayed, thereby delaying the submission of product candidates for regulatory approval or the market introduction and subsequent sales of products. Any such delay may have a material adverse effect on our business, financial condition and results of operations.

Because our clinical development activities rely heavily on sensitive and personal information, an area which is highly regulated by privacy laws, we may not be able to generate, maintain or access essential patient samples or data to continue our research and development efforts in the future on reasonable terms and conditions, which may adversely affect our business.

As a result of our clinical development, we will have access to very sensitive data regarding the patients enrolled in our clinical trials. This data will contain information that is personal in nature. The maintenance of this data is subject to certain privacy-related laws, which impose upon us administrative and financial burdens, and litigation risks. For instance, the rules promulgated by the Department of Health and Human Services under the Health Insurance Portability and Accountability Act, or HIPAA, creates national standards to protect patients' medical records and other personal information in the United

States. These rules require that healthcare providers and other covered entities obtain written authorizations from patients prior to disclosing protected health care information of the patient to companies like NovaBay. If the patient fails to execute an authorization or the authorization fails to contain all required provisions, then we will not be allowed access to the patient's information and our research efforts can be substantially delayed. Furthermore, use of protected health information that is provided to us pursuant to a valid patient authorization is subject to the limits set forth in the authorization (i.e., for use in research and in submissions to regulatory authorities for product approvals). As such, we are required to implement policies, procedures and reasonable and appropriate security measures to protect individually identifiable health information we receive from covered entities, and to ensure such information is used only as authorized by the patient. Any violations of these rules by us could subject us to civil and criminal penalties and adverse publicity, and could harm our ability to initiate and complete clinical studies required to support regulatory applications for our proposed products. In addition, HIPAA does not replace federal, state, or other laws that may grant individuals even greater privacy protections. We can provide no assurance that future legislation will not prevent us from generating or maintaining personal data or that patients will consent to the use of their personal information, either of which may prevent us from undertaking or publishing essential research. These burdens or risks may prove too great for us to

reasonably bear, and may adversely affect our ability to function profitably in the future.

We may be subject to fines, penalties, injunctions and other sanctions if we are deemed to be promoting the use of our products for non-FDA-approved, or off-label, uses.

Our business and future growth depend on the development, use and ultimate sale of products that are subject to FDA regulation, clearance and approval. Under the U.S. Federal Food, Drug, and Cosmetic Act and other laws, we are prohibited from promoting our products for off-label uses. This means that we may not make claims about the safety or effectiveness of our products and may not proactively discuss or provide information on the use of our products, except as allowed by the FDA.

There is a risk that the FDA or other federal or state law enforcement authorities could determine that the nature and scope of our sales and marketing activities may constitute the promotion of our products for a non-FDA-approved use in violation of applicable law. We also face the risk that the FDA or other regulatory authorities might pursue enforcement based on past activities that we have discontinued or changed, including sales activities, arrangements with institutions and doctors, educational and training programs and other activities.

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Government investigations concerning the promotion of off-label uses and related issues are typically expensive, disruptive and burdensome and generate negative publicity. If our promotional activities are found to be in violation of applicable law or if we agree to a settlement in connection with an enforcement action, we would likely face significant fines and penalties and would likely be required to substantially change our sales, promotion, grant and educational activities. In addition, were any enforcement actions against us or our senior officers to arise, we could be excluded from participation in U.S. government healthcare programs such as Medicare and Medicaid.

If we are unable to protect our intellectual property, our competitors could develop and market products similar to ours that may reduce demand for our products.

Our success, competitive position and potential future revenues will depend in significant part on our ability to protect our intellectual property. We rely on the patent, trademark, copyright and trade secret laws of the United States and other countries, as well as confidentiality and nondisclosure agreements, to protect our intellectual property rights. We apply for patents covering our technologies as we deem appropriate.

NovaBay aggressively protects and enforces its patent rights worldwide. However, certain risks remain. There is no assurance that patents will issue from any of our applications or, for those patents we have or that do issue, that the claims will be sufficiently broad to

protect our proprietary rights, or that it will be economically possible to pursue sufficient numbers of patents to afford significant protection. For example, we do not have any composition of matter patent directed to the NVC-101 composition. If a potential competitor introduces a similar method of using NVC-101 with a similar composition that does not fall within the scope of the method of treatment claims, then we or a potential marketing partner would be unable to rely on the allowed claims to protect its market position for the method of using the NVC-101 composition, and any revenues arising from such protection would be adversely impacted.

In addition, there is no assurance that any patents issued to us or licensed or assigned to us by third parties will not be challenged, invalidated, found unenforceable or circumvented, or that the rights granted thereunder will provide competitive advantages to us. If we or our collaborators or licensors fail to file, prosecute or maintain certain patents, our competitors could market products that contain features and clinical benefits similar to those of any products we develop, and demand for our products could decline as a result. Further, although we have taken steps to protect our intellectual property and proprietary technology, third parties may be able to design around our patents or, if they do infringe upon our technology, we may not be successful or have sufficient resources in pursuing a claim of infringement against those third parties. Any pursuit of an infringement claim by us may involve substantial expense and diversion of management attention.

We also rely on trade secrets and proprietary know-how that we seek to protect by confidentiality agreements with our employees, consultants and collaborators. If these agreements are not enforceable, or are breached, we may not have adequate remedies for any breach, and our trade secrets and proprietary know-how may become known or be independently discovered by competitors.

We operate in the State of California. The laws of the State prevent us from imposing a delay before an employee who may have access to trade secrets and proprietary know-how can commence employment with a competing company. Although we may be able to pursue legal action against competitive companies improperly using our proprietary information, we may not be aware of any use of our trade secrets and proprietary know-how until after significant damage has been done to our company.

Furthermore, the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States. If our intellectual property does not provide significant protection against foreign or domestic competition, our competitors, including generic manufacturers, could compete more directly with us, which could result in a decrease in our market share. All of these factors may harm our competitive position.

If bacteria develop resistance to Aganocide compounds, our revenues could be significantly reduced.

Based on our understanding of the hypothesis of the mechanism of action of our Aganocide compounds, we do not expect bacteria to be

able to develop resistance to Aganocide compounds. However, we cannot assure you that one or more strains of bacteria will not develop resistance to our compounds, either because our hypothesis of the mechanism of action is incorrect or because a strain of bacteria undergoes some unforeseen genetic mutation that permits it to survive. Since we expect lack of resistance to be a major factor in the commercialization of our product candidates, the discovery of such resistance would have a major adverse impact on the acceptability and sales of our products.

If physicians and patients do not accept and use our products, we will not achieve sufficient product revenues and our business will suffer.

Even if the FDA approves product candidates that we develop, physicians and patients may not accept and use them. Acceptance and use of our products may depend on a number of factors including:

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- perceptions by members of the healthcare community, including physicians, about the safety and effectiveness of our products;
- published studies demonstrating the cost-effectiveness of our products relative to competing products;
- availability of reimbursement for our products from government or healthcare payers; and
- effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

The failure of any of our products to find market acceptance would harm our business and could require us to seek additional financing.

If we are unable to develop our own sales, marketing and distribution capabilities, or if we are not successful in contracting with third parties for these services on favorable terms, or at all, revenues from any products we develop could be disappointing.

We currently have no internal sales, marketing or distribution capabilities. In order to commercialize any product candidates approved by the FDA, we will either have to develop such capabilities internally or collaborate with third parties who can perform these services for us. If we decide to commercialize any products we develop, we may not be able to hire the necessary experienced personnel and build sales, marketing and distribution operations which are capable of successfully launching new products and generating sufficient product revenues. In addition, establishing such operations will take time

and involve significant expense.

If we decide to enter into co-promotion or other licensing arrangements with third parties, we may be unable to identify acceptable partners because the number of potential partners is limited and because of competition from others for similar alliances with potential partners. Even if we are able to identify one or more acceptable partners, we may not be able to enter into any partnering arrangements on favorable terms, or at all. If we enter into any partnering arrangements, our revenues are likely to be lower than if we marketed and sold our products ourselves.

In addition, any revenues we receive would depend upon our partners' efforts which may not be adequate due to lack of attention or resource commitments, management turnover, change of strategic focus, further business combinations or other factors outside of our control. Depending upon the terms of our agreements, the remedies we have against an under-performing partner may be limited. If we were to terminate the relationship, it may be difficult or impossible to find a replacement partner on acceptable terms, or at all.

If we cannot compete successfully for market share against other companies, we may not achieve sufficient product revenues and our business will suffer.

The market for our product candidates is characterized by intense competition and rapid technological advances. If our product candidates receive FDA approval and are launched they will compete with a number of existing and future drugs, devices and therapies developed,

manufactured and marketed by others. Existing or future competing products may provide greater therapeutic convenience or clinical or other benefits for a specific indication than our products, or may offer comparable performance at a lower cost. If our products are unable to capture and maintain market share, we may not achieve sufficient product revenues and our business will suffer.

We will compete for market share against fully integrated pharmaceutical and medical device companies or other companies that develop products independently or collaborate with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. In addition, many of these competitors, either alone or together with their collaborative partners, have substantially greater capital resources, larger research and development staffs and facilities, and greater financial resources than we do, as well as significantly greater experience in:

- developing drugs and devices;
- conducting preclinical testing and human clinical trials;
- obtaining FDA and other regulatory approvals of product candidates;
- formulating and manufacturing products; and

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- launching, marketing, distributing and selling products.

Our competitors may:

- develop and patent processes or products earlier than we will;
- develop and commercialize products that are less expensive or more efficient than any products that we may develop;
- obtain regulatory approvals for competing products more rapidly than we will; and
- improve upon existing technological approaches or develop new or different approaches that render any technology or products we develop obsolete or uncompetitive.

We cannot assure you that our competitors will not succeed in developing technologies and products that are more effective than any developed by us or that would render our technologies and any products we develop obsolete. If we are unable to compete successfully against current or future competitors, we may be unable to obtain market acceptance for any product candidates that we create, which could prevent us from generating revenues or achieving profitability and could cause the market price of our common stock to decline.

Our ability to generate revenues from any products we develop will be diminished if we fail to obtain acceptable prices or an adequate level of reimbursement for our products from healthcare payers.

Our ability to commercialize our product candidates will depend, in part, on the extent to which

health insurers, government authorities and other third-party payers will reimburse the costs of products which may be developed by us or our partners. We expect that a portion of our economic return from partnering arrangements with pharmaceutical companies and other collaborators will be derived from royalties, fees or other revenues linked to final sales of products that we or our partners develop. Newly-approved pharmaceuticals and other products which are developed by us or our partners will not necessarily be reimbursed by third-party payers or may not be reimbursed at levels sufficient to generate significant sales. Government and other third-party payers are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for new drugs or medical devices. Cost control initiatives such as these could adversely affect our or our collaborators' ability to commercialize products. In addition, real or anticipated cost control initiatives for final products may reduce the willingness of pharmaceutical companies or other potential partners to collaborate with us on the development of new products.

Significant uncertainty exists as to the reimbursement status of newly-approved healthcare products. Healthcare payers, including Medicare, health maintenance organizations and managed care organizations, are challenging the prices charged for medical products or are seeking pharmacoeconomic data to justify formulary acceptance and reimbursement practices. We currently have not generated pharmacoeconomic data on

any of our product candidates. Government and other healthcare payers increasingly are attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for drugs and medical devices, and by refusing, in some cases, to provide coverage for uses of approved products for disease indications for which the FDA has or has not granted labeling approval. Adequate third-party insurance coverage may not be available to patients for any products we discover and develop, alone or with collaborators. If government and other healthcare payers do not provide adequate coverage and reimbursement levels for our products, market acceptance of our product candidates could be limited.

Risks Relating to Owning Our Common Stock

The price of our common stock may fluctuate substantially, which may result in losses to our shareholders.

The stock prices of many companies in the pharmaceutical and biotechnology industry have generally experienced wide fluctuations, which are often unrelated to the operating performance of those companies. The market price of our common stock is likely to be volatile and could fluctuate in response to, among other things:

- the results of preclinical or clinical trials relating to our product candidates;
- the announcement of new products by us or our competitors;
- announcement of partnering arrangements by us or our competitors;
- quarterly variations in our or our competitors' results of operations;

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- announcements by us related to litigation;
- changes in our earnings estimates, investors' perceptions, recommendations by securities analysts or our failure to achieve analysts' earning estimates;
- developments in our industry; and
- General, economic and market conditions, including the recent volatility in the financial markets and decrease in consumer confidence and other factors unrelated to our operating performance or the operating performance of our competitors.

The volume of trading of our common stock may be low, leaving our common stock open to risk of high volatility.

The number of shares of our common stock being traded may be very low. Any shareholder wishing to sell his/her stock may cause a significant fluctuation in the price of our stock. In addition, low trading volume of a stock increases the possibility that, despite rules against such activity, the price of the stock may be manipulated by persons acting in their own self-interest. We may not have adequate market makers and market making activity to prevent manipulation.

Our directors, executive officers and principal shareholders have significant voting power and may take actions that may not be in the best interests of our other shareholders.

As of December 31, 2008, our officers and directors collectively controlled approximately 3,979,097 shares of our outstanding common stock (and

approximately 5,183,520 shares of our common stock when including options held by them which were exercisable as of or within 60 days of December 31, 2008). Furthermore, as of December 31, 2008, our largest shareholder, a family trust established and controlled by Dr. Ramin Najafi, our Chairman and Chief Executive Officer, beneficially owned 3,126,700 shares or 14.6% of our outstanding common stock. As a result, Dr. Najafi can significantly influence the management and affairs of our company and most matters requiring shareholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control and might adversely affect the market price of our common stock. This concentration of ownership may not be in the best interests of our other shareholders.

Future sales of shares by our shareholders could cause the market price of our common stock to drop significantly, even if our business is doing well.

Up to 2,972,275 shares held by certain of our officers and directors will become eligible for sale in the public market over the period ending October 25, 2009, as the shares are released from lock-up agreements with the underwriters in our initial public offering.

In addition, at any time and without public notice, we and the underwriters may release, at our respective discretions, all or some of the securities subject to our respective lock-up agreements, subject to applicable regulatory requirements. As restrictions on resale end,

the market price of our stock could drop significantly if the holders of those shares sell them or are perceived by the market as intending to sell them. These declines in our stock price could occur even if our business is otherwise doing well.

Our limited operating history may make it difficult for you to evaluate our business and to assess our future viability.

Our operations to date have been limited to organizing and staffing our company, developing our technology, researching and developing our compounds, and conducting preclinical studies and early-stage clinical trials of our compounds. We have not demonstrated the ability to succeed in achieving clinical endpoints, obtain regulatory approvals, formulate and manufacture products on a commercial scale or conduct sales and marketing activities. Consequently, any predictions you make about our future success or viability are unlikely to be as accurate as they could be if we had a longer operating history.

Our amended and restated articles of incorporation and bylaws and California law, contain provisions that could discourage a third party from making a takeover offer that is beneficial to our shareholders.

Anti-takeover provisions of our amended and restated articles of incorporation, amended and restated bylaws and California law may have the effect of deterring or delaying attempts by our shareholders to remove or replace management, engage in proxy contests and effect changes in control. The provisions of our charter documents include:

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- a classified board so that only one of the three classes of directors on our Board of Directors is elected each year;
- elimination of cumulative voting in the election of directors;
- procedures for advance notification of shareholder nominations and proposals;
- the ability of our Board of Directors to amend our bylaws without shareholder approval; and
- the ability of our Board of Directors to issue up to 5,000,000 shares of preferred stock without shareholder approval upon the terms and conditions and with the rights, privileges and preferences as our Board of Directors may determine.

In addition, as a California corporation, we are subject to California law, which includes provisions that may have the effect of deterring hostile takeovers or delaying or preventing changes in control or management of our company. Provisions of the California Corporations Code could make it more difficult for a third party to acquire a majority of our outstanding voting stock by discouraging a hostile bid, or delaying, preventing or deterring a merger, acquisition or tender offer in which our shareholders could receive a premium for their shares, or effect a proxy contest for control of NovaBay or other changes in our management.

We have not paid dividends in the past and do not expect to pay dividends in the future, and any return on investment may be limited to the value of our stock.

We have never paid cash dividends on our common stock and do not anticipate paying cash dividends on our common stock in the foreseeable future. The payment of dividends on our common stock will depend on our earnings, financial condition and other business and economic factors affecting us at such time as our Board of Directors may consider relevant. If we do not pay dividends, you will experience a return on your investment in our shares only if our stock price appreciates. We cannot assure you that you will receive a return on your investment when you do sell your shares or that you will not lose the entire amount of your investment.

We may be considered a "foreign investment entity" which may have adverse Canadian tax consequences for our Canadian investors.

Although we believe that we are not currently a "foreign investment entity" within the meaning of the Canadian tax laws, no assurances can be given in this regard or as to our status in the future. If we become a "foreign investment entity" within the meaning of the Canadian tax laws, there may be certain adverse tax consequences for our Canadian investors.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this amendment report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: August 4, 2009

NOVABAY PHARMACEUTICALS, INC.

By: /S/ THOMAS J. PAULSON
THOMAS J. PAULSON
Chief Financial Officer and Treasurer

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EXHIBIT INDEX

Exhibit No.	Description
3.1	Amended and Restated Articles of Incorporation of registrant (Incorporated by reference to the exhibit of the same number from the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2007 as filed with the SEC on November 15, 2007.)
3.2	Amended and Restated Bylaws of registrant (Incorporated by reference to the exhibit of the same number from the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2007 as filed with the SEC on November 15, 2007.)
4.1*	Specimen common stock certificate
4.2**	Form of Registration Rights Agreement by and between the Registrant and the underwriters
10.1*+	2002 Stock Option Plan, and forms of agreements thereto
10.2*+	2005 Stock Option Plan, and forms of agreements thereto
10.3*+	2007 Omnibus Incentive Plan, and forms of agreements thereto (the Plan is incorporated by reference to Exhibit 10.1 from the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2008 as filed with the SEC on August 14, 2008, and the forms of agreements thereto are incorporated by reference to the exhibit referencing the Plan from the Company's amendment to registration statement of Form S-1 (File No. 333-140714) filed with the Securities and Exchange Commission on May 29, 2007, as amended.)
10.4*+	Employment Agreement dated January 1, 2007 by and between the Registrant

	and Ramin (“Ron”) Najafi
10.5*+	Employment Agreement dated January 1, 2007 by and between the Registrant and John (“Jack”) O’Reilly
10.6*+	Employment Agreement dated January 1, 2007 by and between the Registrant and Behzad Khosrovi
10.7*+	Employment Agreement dated January 1, 2007 by and between the Registrant and Colin Scott
10.8+	Employment Agreement dated January 9, 2008 by and between the Registrant and Thomas J. Paulson (Incorporated by reference to Exhibit 10.18 from the company’s annual report on Form 10-K for the year end December 31, 2007 as filed with the SEC on March 14, 2008.)
10.9+	Retirement and Consulting Agreement dated January 1, 2009 by and Between the Registrant and John (“Jack”) O’Reilly (previously filed with the original filing of this Form 10-K)
10.10*	Office Lease dated June 3, 2004 by and between the Registrant and Emery Station Associates II, LLC, as amended
10.11*+	Collaboration and License Agreement dated August 29, 2006 by and between the Registrant and Alcon Manufacturing, Ltd.
10.12*	Financial Advisory and Investor Relations Consulting Agreement dated February 13, 2007 by and between the Registrant and PM Holdings Ltd
10.13*	Director Compensation Plan
10.14*	Master Security Agreement dated April 23, 2007 by and between the Registrant and General Electric Capital Corporation
10.15*	License Agreement dated June 11, 2007 by and between the Registrant and KCI International VOF GP
10.16*	

	Form of Common Stock Purchase Warrant by and between the Registrant and the underwriters
10.17	Fifth Amendment dated November 20, 2007 to Office Lease dated June 3, 2004 by and between the Registrant and Emery Station Associates II, LLC, as amended (Incorporated by reference to Exhibit 10.20 from the Company's annual report on Form 10-K for the year ended December 31, 2007 as filed with the SEC on March 14, 2008.)
10.18	Sixth Amendment to Lease between Emery Station Office II, LLC and Novacal Pharmaceuticals, Inc., effective September 1, 2008. (Incorporated by reference to Exhibit 10.1 from the Company's quarterly report on Form 10-Q/A for the quarter ended September 30, 2008 as filed with the SEC on November 14, 2008.)
23.1 †€	Consent of Davidson & Company LLP
24.1	Power of Attorney (included on the signature pages of the Form 10-K as previously filed)
31.1	Certification of the principal executive officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of the principal financial officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of the chief executive officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (previously filed with the original filing of this Form 10-K)
32.2	Certification of the chief financial officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (previously filed with the original filing of this Form 10-K)

*

Incorporated by reference to the exhibit of the same number from the Company's registration statement of Form S-1 (File No. 333-140714) initially filed with the Securities and Exchange Commission on February 14, 2007, as amended.

** Incorporated by reference Exhibit 10.7 from the Company's registration statement of Form S-1 (File No. 333-140714) initially filed with the Securities and Exchange Commission on February 14, 2007, as amended.

+ Indicates a management contract or compensatory plan or arrangement.

† NovaBay Pharmaceuticals, Inc. has been granted confidential treatment with respect to certain portions of this exhibit (indicated by asterisks), which have been separately filed with the Securities and Exchange Commission.

††Previously Filed.