AmpliPhi Biosciences Corp
Form 10-K/A
May 23, 2014

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K/A

AMENDMENT NO. 1 TO
ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

For the Fiscal Year Ended December 31, 2013

Commission File Number 000-23930

AMPLIPHI BIOSCIENCES CORPORATION

(Exact name of registrant as specified in its charter)

Washington	91-1549568
(State or other jurisdiction of incorporation and organization)	(I.R.S. Employer Identification No.)

4870 Sadler Road, Suite 300
Glen Allen, Virginia 23060

(Address of principal executive offices, including zip code)

(804) 205-5069

(Registrant s telephone number)

Securities registered pursuant to Section 12(b) of the Act:
None
Securities registered pursuant to Section 12(g) of the Act:
Common Stock, par value $0.01 per share
(Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.Yes o No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act.Yes o No x

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.Yes x No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).Yes x No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. o

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 definitions of large accelerated filer, accelerated filer, and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer o Accelerated filer o
Non-accelerated filer o (Do not check if a smaller reporting company) Smaller reporting company x

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

As of June 30, 2013, the aggregate market value of voting stock held by non-affiliates of the Registrant, based on the closing price of the Common Stock on June 28, 2013 as reported on the OTC Pink market, was approximately $10,122,521. Shares of Common Stock held by each officer and director and by each person who owns 5% or more of the outstanding Common Stock have been excluded from this computation in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 24, 2014, the Registrant had outstanding 182,535,562 shares of Common Stock.

Documents incorporated by reference: Portions of the Registrant s proxy statement to be filed pursuant to Regulation 14A within 120 days after Registrant s fiscal year end of December 31, 2013 are incorporated herein by reference into Items 10, 11, 12, 13 and 14 of Part III of this annual report.

TABLE OF CONTENTS

TABLE OF CONTENTS

AMPLIPHI BIOSCIENCES CORPORATION

TABLE OF CONTENTS

EXPLANATORY NOTE REGARDING AMENDMENT AND RESTATEMENT

Unless the context otherwise requires, we use the terms AmpliPhi Biosciences, AmpliPhi, we, us, the Company and our in this report to refer to AmpliPhi Biosciences Corporation and its subsidiaries.

We are filing this Amendment No. 1 to our Annual Report on Form 10-K to Amend and Restate Item 7, Management s Discussion and Analysis of Financial Condition and Results of Operations and Item 8, Financial Statements and Supplementary Data. Other than these changes, the Annual Report is not being amended.

This Annual Report on Form 10-K includes restatement of the following previously filed consolidated financial statements and data (and related disclosures): our consolidated balance sheets as of December 31, 2013, and our consolidated statements of operations and comprehensive loss, consolidated statement of stockholders equity (deficit), and consolidated statement of cash flows for the fiscal year ended December 31, 2013.

The Company s previously issued December 31, 2013 financial statements have been restated to net investment fees paid as part of the December financing against the proceeds received. As a result of this correction, we reduced general and administrative expenses and additional paid in capital by $2,550,000. The Company s net loss decreased $2,550,000 to $55,861,000. The net loss per share decreased by $0.02 per share to $(0.64) per share.

For more information regarding these restatements, please refer to Item 7, Management s Discussion and Analysis of Financial Condition and Results of Operations and Note 14 (Correction of Errors) in Notes to Consolidated Financial Statements Year Ended December 31, 2013.

TABLE OF CONTENTS

Item 7. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the consolidated financial statements and the related notes contained elsewhere in this Annual Report. Some of the information contained in this discussion and analysis are set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. See Special Note Regarding Forward-Looking Statements. Our actual results may differ substantially from those referred to herein due to a number of factors, including but not limited to risks described in the section entitled Risk Factors and elsewhere in this Annual Report.

Restatement

As discussed in the Explanatory Note Regarding Amendment and Restatement and Note 14 (Correction of Errors) to Notes to Consolidated Financial Statements Year Ended December 31, 2013 included in this Annual Report on Form 10-K/A, we are amending and restating our audited consolidated financial statements and related disclosures for the year ended December 31, 2013.

The following discussion and analysis of our financial condition and results of operations incorporates the restated amounts. For this reason, the data set forth in this section may not be comparable to discussion and data in our previously filed Annual Report on Form 10-K for the year ended December 31, 2013.

Overview

AmpliPhi Biosciences is a biotechnology company focused on the discovery, development and commercialization of novel phage therapeutics. Our proprietary pipeline is based on the use of bacteriophages, a family of viruses that infect only bacteria. Phages have powerful and highly selective mechanisms of action that permit them to target and kill specific bacterial pathogens, including the so-called multi-drug-resistant (MDR) or Superbug strains.

We are combining our proprietary approach and expertise in identifying, characterizing and developing naturally occurring bacteriophages with that of our collaboration partners in bacteriophage biology, drug engineering, development and manufacturing, to develop second-generation bacteriophage products. We believe that phages represent a promising means to treat bacterial infections, especially those that have developed resistance to current medicines.

Our lead programs consist of three product candidates: AmpliPhage-001 for the treatment of *P. aeruginosa* lung infections in cystic fibrosis (CF) patients; AmpliPhage-002, for the treatment of methicillin-resistant *S. aureus* (MRSA) infections; and AmpliPhage-004 for the treatment of *C. difficile* infections.

We have incurred net losses since our inception. Our operations to date have been limited to research and development and raising capital. Since November 2010, we have raised approximately $5.6 million through the sale and issuance of convertible notes and warrants to purchase common stock. In June and July of 2013, we completed a private placement of shares of our Series B Convertible Preferred Stock and warrants to purchase common stock, which raised approximately $7.0 million in addition to converting approximately $6.3 million in outstanding convertible notes. In December 2013, we completed a private placement of shares of our common stock, which raised approximately $18 million, prior to commissions. To date, we have not generated any revenue and have primarily

financed our operations through the sale and issuance of convertible notes and the private placement of our equity securities. As of December 31, 2013, we had a deficit accumulated of $384.7 million. We recorded annual net losses of $55.9 million in 2013 and $1.1 million in 2012. We anticipate that a substantial portion of our capital resources and efforts in the foreseeable future will be focused on completing the development and obtaining regulatory approval of our product candidates.

We expect our research and development expenses to increase as we pursue regulatory approval for our product candidates. We also expect to incur additional expenses associated with operating as a public company. As a result, we expect to continue to incur significant and increasing operating losses at least for the next several years. We do not expect to generate product revenue unless and until we successfully complete development and obtain marketing approval for at least one of our product candidates.

TABLE OF CONTENTS

We currently expect to use our existing cash and cash equivalents for the continued research and development of our product candidates and for working capital and other general corporate purposes.

We may also use a portion for the potential acquisition of, or investment in, product candidates, technologies, formulations or companies that complement our business, although we have no current understandings, commitments or agreements to do so. We expect that these funds will not be sufficient to enable us to complete all necessary development of any potential product candidates. Accordingly, we will be required to obtain further funding through other public offerings, debt financing, collaboration and licensing arrangements or other sources. Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs.

Financial Operations Overview

Revenue

To date, we have not generated any revenue from the sale of our product candidates and do not expect to generate any revenue from the sale of our product candidates in the near term. In the last two years, we recognized $1.0 million in revenue related to license agreements and grants from governments and academic institutions. These revenues were used in our new focus, the development of phages.

Research and Development Expenses

Research and development costs consist of the costs associated with our research and discovery activities, conducting clinical trials, manufacturing development efforts and activities related to regulatory filings. Our research and development expenses consist of salaries, non-cash stock-based compensation, costs of outside collaborators and outside services, royalty and license costs and facility, occupancy and utility expenses. We expense research and development costs as incurred. We expect annual research and development expenses will increase significantly in the future as we progress with development. In the last two years, we incurred an aggregate of $8.0 million on research and development expenses, including non-cash stock-based compensation expense.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for our personnel in the executive, finance, patent, accounting and other administrative functions, including non-cash stock-based compensation, as well as consulting costs for functions for which we either do not or only partially staff internally, including public relations, market research and recruiting. Other costs include professional fees for legal and accounting services, insurance and facility costs. In the last two years, we incurred an aggregate of $9.5 million in general and administrative expenses, including non-cash stock-based compensation expense.

Interest Income (Expense)

Interest income consists of interest earned on our cash and cash equivalents and is not considered significant to our financial statements. We expect our interest income to increase in the future as we raise further capital to fund our operations.

Critical Accounting Policies and Use of Estimates

Our management s discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

TABLE OF CONTENTS

Goodwill

Costs of investments in purchased companies in excess of the underlying fair value of net assets at the date of acquisition are recorded as goodwill and assessed annually for impairment. If considered impaired, goodwill will be written down to fair value and a corresponding impairment loss recognized. As of December 31, 2013, we have recorded goodwill of $4.3 million due to the 2012 acquisition of SPH s know-how and phage libraries and the 2011 acquisition of Biocontrol s patents and phage library. In management s opinion, no goodwill has been impaired as of December 31, 2013.

Research and Development Costs

In Process Research & Development (IPR&D) assets represent capitalized incomplete research projects that the Company acquired through business combinations. Such assets are initially measured at their acquisition date fair values. The fair value of the research projects is recorded as intangible assets on the consolidated balance sheet rather than expensed regardless of whether these assets have an alternative future use. The amounts capitalized are being accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of research and development efforts associated with the projects. Upon successful completion of each project, the Company will make a determination as to the then remaining useful life of the intangible asset and begin amortization. The Company tests its indefinite-lived intangibles, including IPR&D assets, for impairment at least quarterly. As of December 31, 2013, we have recorded IPR&D of $12.9 million due to the 2012 acquisition of SPH s know-how and phage libraries and the 2011 acquisition of Biocontrol s patents and phage library. In management s opinion, no IPR&D has been impaired as of December 31, 2013.

Stock-Based Compensation Expenses

We account for stock options and restricted stock units related to our Stock Incentive Plans under the provisions of ASC 718, which requires the recognition of the fair value of stock-based compensation. The fair value of stock options and restricted stock units was estimated using a Black-Scholes option valuation model. This model requires the input of subjective assumptions in implementing ASC 718, including expected dividend, expected life, expected volatility and forfeiture rate of each award, as well as the prevailing risk-free interest rate and the fair value of the underlying common stock on the date of grant. The fair value of equity-based awards is amortized over the vesting period of the award, and we have elected to use the straight-line method of amortization. Actual results could differ from our assumptions, which may cause us to record adjustments to increase or decrease compensation expense, in future periods. The assumptions used in the Black-Scholes option valuation model for the years ended December 31, 2013 and 2012 are set forth below.

The following are the assumptions for the periods in which we granted stock options:

Expected Dividend: We do not anticipate any dividends.

Expected Life: The expected life represents the period that we expect our stock-based awards to be outstanding. We determine life based on historical experience and vesting schedules of similar awards.

Expected Volatility: Our expected volatility represents the weighted average historical volatility of the shares of our common stock for the most recent four-year and five-year periods.

Risk-Free Interest Rate: We base the risk-free interest rate used on the implied yield currently available on U.S. Treasury zero-coupon issues with an equivalent remaining term. Where the expected term of our stock-based awards does not correspond with the terms for which interest rates are quoted, we perform a straight-line interpolation to determine the rate from the available term maturities.

Forfeiture Rate: We apply an estimated forfeiture rate that is derived from historical forfeited shares. If the actual number of forfeitures differs from our estimates, we may record additional adjustments to compensation expense in future periods.

TABLE OF CONTENTS

The weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of the stock option grants were as follows:

	Years Ended December 31,	
	2013	2012
Risk-free interest rate	1.13 %	0.6 %
Expected volatility	160.9 %	172.1 %
Expected term (in years)	4.0	4.0
Expected dividend yield	0.0 %	0.0 %

Warrant and Preferred Shares Conversion Feature Liability

We account for warrants and the preferred shares conversion feature with anti-dilution (down-round) provisions under the guidance of ASC 815, Derivatives and Hedging and Emerging Issue Task Force Statement 07-5: Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock, which require the warrants and the preferred shares conversion feature to be recorded as a liability and adjusted to fair value in each reporting period. We estimate the fair values of these securities using a Black Scholes valuation model.

Accounting for Income Taxes

Our income tax policy records the estimated future tax effects of temporary differences between the tax basis of assets and liabilities and amounts reported in the accompanying balance sheets, as well as operating loss and tax credit carry-forwards. We have recorded a full valuation allowance to reduce our deferred tax assets, as based on available objective evidence; it is more likely than not that the deferred tax assets will not be realized. In the event that we were to determine that we would be able to realize our deferred tax assets in the future, an adjustment to the deferred tax assets would increase net income in the period such determination was made.

Recent Accounting Pronouncements

In September 2011, the FASB issued Accounting Standards Update (ASU) no. 2011-08, Intangibles Goodwill and Other (Topic 350): Testing Goodwill for Impairment that simplifies how public and nonpublic entities test goodwill for impairment. The amendments permit an entity to first assess qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform the two-step goodwill impairment test described in ASC Topic 350. The more-likely-than-not threshold is defined as having a likelihood of more than 50%. The guidance also includes examples of the types of events and circumstances to consider in conducting the qualitative assessment. The amendments will be effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. We elected to early adopt this standard and used these new guidelines in assessing goodwill impairment for the consolidated financial statements.

On May 16, 2013, the FASB issued a proposed Accounting Standards Update, Leases (Topic 842): a revision of the 2010 proposed Accounting Standards Update, Leases (Topic 840). The proposal affects operating leases, especially with properties, and requires lessees to recognize assets and liabilities arising from those leases. The draft also proposes changes in accounting for purchase options and contingent rentals, which would affect the measurement of assets and liabilities for capital leases. An entity will be required to recognize all outstanding leases within the scope of the draft as of the date of initial application using a simplified retroactive approach. The exposure draft proposes

that lessee and lessors should apply a right-of-use model in accounting for all leases, with few exceptions. An entity has a right to use an asset if it has control over the asset which is fulfilled if one of the three conditions outlined in the document are met. For leases within the scope of the draft, a lessee would recognize a right of use asset representing its right to use and the liability to make lease payments. A lessor would recognize an asset representing its right to receive lease payments using a performance obligation approach or a derecognition approach depending on its exposure to risks. There are numerous disclosures that would also be required such as a reconciliation of the opening and closing balances for the leased asset and liabilities. This proposed guidance could impact all companies that participate in leasing activities. We do not believe this proposed accounting standard will have a significant impact on the Company s future financial reporting.

TABLE OF CONTENTS

JOBS Act

In April 2012, the JOBS Act was signed into law. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an emerging growth company. As an emerging growth company, we are electing not to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards, and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Section 107 of the JOBS Act provides that our decision not to take advantage of the extended transition period is irrevocable. In addition, we are in the process of evaluating the benefits of relying on the other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, if as an emerging growth company we choose to rely on such exemptions, we may not be required to, among other things, (i) provide an auditor s attestation report on our system of internal controls over financial reporting pursuant to Section 404, (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act, (iii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding a supplement to the auditor s report providing additional information about the audit and the financial statements (auditor discussion and analysis) and (iv) disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the Chief Executive Officer s compensation to median employee compensation. These exemptions will apply for a period of five years following the completion of our initial public offering or until we no longer meet the requirements of being an emerging growth company, whichever is earlier.

Results of Operations

Comparison of the Years Ended December 31, 2013 and 2012

Revenue

For the years ended December 31, 2013 and 2012, we recognized $0.3 million and $0.7 million in revenue, respectively. For the years ended December 31, 2013 and 2012, we earned $0.3 million and $0.6 million of revenue through sublicensing agreements involving our former gene therapy program, respectively. For the year ended December 31, 2012, we also earned $0.1 million in grant revenue.

Research and Development

Research and development expenses were $6.5 million for the year ended December 31, 2013, compared to $1.5 million for the year ended December 31, 2012. The $5.0 million increase in expenses is due to an increase in discovery, laboratory, nonclinical testing, research and development collaborations, consulting and clinical development planning expenses for all of our product candidates.

Research and development expenses are expected to increase in 2014 compared to 2013 as we plan to continue devoting substantial resources to research and development in future periods as we start clinical trials and continue our discovery efforts.

General and Administrative

General and administrative expenses were $6.3 million for 2013, compared to $3.2 million for 2012. The $3.1 million increase is due to $1.0 million in placement agent fees associated with the June 2013 Series B Preferred Shares placement, $0.7 million in higher legal expenses due to preparation to become a public company, and $1.4 million in higher staffing and outside consulting expenses (including non-cash compensation expense related to options granted to Company executives).

We currently expect our general and administrative expenses to increase in 2014 compared to 2013 due to the costs associated with being a public company.

Discontinued Operations

In June 2012, we sold certain assets used in our gene therapy business including process development, quality control, quality assurance, manufacturing and bioanalytical functions for $3.1 million. In addition to this cash consideration, we may receive a long-term royalty of 1.75% on all product sales. This royalty may be completely canceled at any time by a one-time payment of $1.8 million.

TABLE OF CONTENTS

Interest Income (Expense)

During 2013 and 2012, we issued $2.0 million and $1.0 million in convertible notes, respectively. Interest expense in 2013 was $0.2 million, compared to $0.3 million for 2012. The decrease was due to converting the convertible notes into Series B preferred Shares in June and July 2013 and thus eliminating future interest expense.

Income Taxes

We incurred net operating losses for the years ended December 31, 2013 and 2012 and, accordingly, we did not pay any federal or state income taxes. As of December 31, 2013, we had accumulated approximately $175.4 million in U.S. and UK operating loss carry-forwards and research tax credit carry-forwards of approximately $3.7 million. The carry-forwards began to expire in 2012. Our net operating loss carry-forwards are subject to certain limitations on annual utilization as a result of changes in ownership of the Company, as defined by federal and state tax laws.

Net Operating Losses

We have not recorded a benefit from our net operating loss or research credit carry-forwards because we believe that it is uncertain that we will have sufficient income from future operations to realize the carry-forwards prior to their expiration. Accordingly, we have established a 100% valuation allowance against the deferred tax asset arising from the carry-forwards.

Liquidity and Capital Resources

We have incurred net losses since inception through December 31, 2013 of $384.7 million, of which $315.5 million was incurred in the Company s prior focus of gene therapy in 2010 and years earlier. We have not generated any product revenues and do not expect to generate revenue from the sale of product candidates in the near term.

We had cash of $20.4 million and $0.9 million at December 31, 2013 and 2012, respectively.

Net cash used in operating activities for the years ended December 31, 2013 and 2012 was $6.3 million and $4.3 million, respectively. For the year ended December 31, 2013, cash used in operations was attributable to the net loss for the year after adding back non-cash charges for loss on derivative liabilities, shares issued for technology access fee, amortization of loan discount, fair market value of warrants issued as June and July investment fees, stock-based compensation expense, and depreciation expenses. For the year ended December 31, 2012, cash used in operations was attributable to the net loss for the year after adding back non-cash charges for stock-based compensation expense, depreciation expenses and loss on disposal of equipment, offset by a decrease in accrued liabilities and an increase in receivables. Net cash used in investing activities for the year ended December 31, 2013 was $0.1 million due to purchases of equipment. Net cash provided by investing activities for the year ended December 31, 2012 was $3.1 million due to the sale of assets from discontinued operations slightly offset by purchases of property and equipment. Net cash provided by financing activities was $25.9 million for the year ended December 31, 2013, due to the December 2013 private placement, the Series B financing and convertible loan notes. Net cash provided by financing activities was $1.0 million for the year ended December 31, 2012, due to proceeds from convertible notes. We expect 2014 cash requirements to be in the range of $15.0 million to $17.0 million. We believe that our cash as of December 31, 2013, will be sufficient to fund our projected operating requirements into the first quarter of 2015.

We expect to need to raise additional capital or incur indebtedness to continue to fund our future operations. We may

seek to raise capital through a variety of sources, including:

- the public equity market;
- private equity financing;
- collaborative arrangements;
- licensing arrangements; and/or
- public or private debt.

TABLE OF CONTENTS

Our ability to raise additional funds will depend on our clinical and regulatory events, our ability to identify promising in-licensing opportunities and factors related to financial, economic and market conditions, many of which are beyond our control. We cannot be certain that sufficient funds will be available to us when required or on satisfactory terms. If adequate funds are not available, we may be required to significantly reduce or refocus our operations or to obtain funds through arrangements that may require us to relinquish rights to certain of our products, technologies or potential markets, any of which could delay or require that we curtail our development programs or otherwise have a material adverse effect on our business, financial condition and results of operations. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of such securities would result in ownership dilution to our existing stockholders.

If we are unable to secure additional financing on a timely basis or on terms favorable to us, we may be required to cease or reduce certain research and development projects, to sell some or all of our technology or assets or to merge all or a portion of our business with another entity. Insufficient funds may require us to delay, scale back or eliminate some or all of our activities, and if we are unable to obtain additional funding, there is uncertainty regarding our continued existence.

Contractual Obligations and Commitments

In February 2011, the Company entered into an agreement with Virginia Biotechnology Research Partnership Authority for Richmond, Virginia laboratory space. This agreement has a contractual expiration date of February 29, 2012 at which time it converted to a rolling three-month lease. At December 31, 2013, the Company s minimum payment commitment for the Richmond, Virginia laboratory space was $4,800.

In December 2011, the Company entered into an agreement with Nevis Limited and Charter Limited for laboratory space in Bedfordshire, United Kingdom. This agreement has a minimum period of 3 years and a contractual expiration date of December 8, 2016. At December 31, 2013, the Company s minimum payment commitment for the Bedfordshire laboratory space was $127,000.

In February 2013, we entered into an agreement with Office Suites Plus (now Regus Management Group, LLC) for office space in Glen Allen, Virginia. The agreement has a minimum period of one year ending February 28, 2014, at which time it was extended through June 2014, with a monthly cost of $2,555. At December 31, 2013, our minimum payment commitment for the Glen Allen space was $5,110.

In September 2013, we entered into an agreement with PBC Carlsbad, LLC for office space in Carlsbad, California. The agreement has a minimum period of six months ending February 28, 2014, at which time it was extended through August 2014, with a monthly cost of $1,033. At December 31, 2013, our minimum payment commitment for the Carlsbad office space was $2,066.

Off-Balance Sheet Arrangements

As of December 31, 2013, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts. Therefore, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships.

Net Cash Used in Operating Activities

For the year ended December 31, 2013, net cash flow used in operating activities was $6.3 million, compared to net cash flow used in operating activities of $4.3 million for the year ended December 31, 2012. Net cash flow used in operating activities for the year ended December 31, 2013 consisted primarily of a net loss of $55.9 million, increased by $40.6 million for the expense recorded as the change in fair value of warrants, $3.0 million for the Intrexon technology access fee paid by stock, $2.6 million for amortization of loan discount, $1.4 million for stock option expense, $0.6 million for the receipt of tax refund, and $0.2 million for accrued interest on convertible loans. Net cash flow used in operating activities for the year ended December 31, 2012, consisted primarily of net loss of $4.2 million, increased by $0.1 million for the receipt of an AMT license fee receivable and $0.3 million for accrued interest on convertible notes, and decreased by $0.4 million for accounts payable and accrued liabilities.

TABLE OF CONTENTS

Net Cash from Financing Activities

For the year ended December 31, 2013, net cash flow provided by financing activities was $25.9 million, compared to net cash flow provided by financing activities of $1.0 million for the year ended December 31, 2012. Net cash flow provided by financing activities for the year ended December 31, 2013 consisted of $16.9 million received through December 2013 common stock placement, $7.0 million received through the Series B Convertible Preferred Stock issuance, $2.0 million received through the issuance of convertible notes. Net cash flow provided by financing activities for the year ended December 31, 2012, consisted of $1.0 million received through the issuance of convertible notes.

Recent Financings

On December 16, 2013, we entered into subscription agreements to issue an aggregate amount of 72,007,000 shares of common stock for an aggregate purchase price of approximately $18 million as part of a private placement. The purchasers of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of such purchasers was an accredited investor under Rule 506 of Regulation D or not a U.S. person under Regulation S.

On June 26, 2013, we completed a private placement of convertible preferred stock and warrants to purchase common stock with gross proceeds of $7.0 million through the sale of shares of our newly-created Series B Convertible Preferred Stock. As part of the same transaction, approximately $5.5 million in outstanding convertible notes were converted into shares of Series B Convertible Preferred Stock and warrants to purchase common stock. On July 15, 2013, we completed a second closing in which we converted approximately $0.8 million of outstanding convertible notes into Series B Convertible Preferred Stock and warrants to purchase common stock. The financing was led by life-sciences investors RA Capital Management and Third Security, LLC, with participation from BioScience Managers Pty Ltd.

Under the terms of the financing, we issued an aggregate amount of approximately 10.0 million shares of the Series B Convertible Preferred Stock for an aggregate purchase price of approximately $13.3 million (including the conversion of approximately $6.3 million of outstanding convertible notes). Each share of Series B Convertible Preferred Stock is convertible into 10 shares of common stock. Additionally, we issued warrants to purchase an aggregate of up to approximately 25.0 million shares of common stock at an exercise price of $0.14 per share. As a result of the completion of this private placement, as of July 15, 2013, all previously issued convertible notes have been converted and there are no convertible notes outstanding.

Comparison of the Years Ended December 31, 2012 and 2011

Revenue

For the years ended December 31, 2012 and 2011, we recognized $0.7 million and $0.1 million in revenue, respectively. For the years ended December 31, 2012 and 2011, we earned $0.6 million and $0.1 million of revenue through sublicensing agreements involving our former gene therapy program.

For the years ended December 31, 2012 and 2011, we also earned $0.1 million and $20,000 in grant revenue, respectively.

Research and Development

Research and development expenses were $1.5 million for the year ended December 31, 2012, compared to $0.7 million for the year ended December 31, 2011. The $0.8 million increase in expenses is due to an increase in consulting and development expenses.

Research and development expenses are expected to increase in 2013 compared to 2012 as we plan to continue devoting substantial resources to research and development in future periods as we start clinical trials and continue our discovery efforts.

General and Administrative

General and administrative expenses were $3.2 million for 2012, compared to $3.3 million for 2011. The $0.1 million decrease is due to lower administrative staffing and facilities expenses, partially offset by higher legal expenses related to the acquisition of SPH.

TABLE OF CONTENTS

We currently expect our general and administrative expenses to increase in 2013 compared to 2012 due to the costs associated with preparing this registration statement and being a public company.

Discontinued Operations

In June 2012, we sold certain assets used in our gene therapy business including process development, quality control, quality assurance, manufacturing and bioanalytical functions for $3.1 million. In addition to this cash consideration, we may receive a long-term royalty of 1.75% on all product sales. This royalty may be completely canceled at any time by a one-time payment of $1.8 million.

Tax Refund

As of December 31, 2012, we had a United Kingdom research and development tax refund of $0.1 million (£0.1 million) for the losses in the subsidiary based in the United Kingdom, compared to $0.3 million for 2011. The decrease in the refund was due to reduced staffing in 2012 compared to 2011.

Interest Income (Expense)

Interest expense in 2012 was $0.3 million, compared to $0.1 million for 2011. The increase was due to interest accrued for convertible notes. During 2012 and 2011, we issued $1.0 million and $2.7 million in convertible notes, respectively. Interest on the unpaid principal balance of these notes accrues at the rate of ten percent (10%) per annum.

Income Taxes

We incurred net operating losses for the years ended December 31, 2012 and 2011 and, accordingly, we did not pay any federal or state income taxes. As of December 31, 2012, we had accumulated approximately $170.4 million in U.S. and UK operating loss carry-forwards and research tax credit carry-forwards of approximately $4.3 million. The carry-forwards began to expire in 2012. Our net operating loss carry-forwards are subject to certain limitations on annual utilization as a result of changes in ownership of us, as defined by federal and state tax laws.

Net Operating Losses

We have not recorded a benefit from our net operating loss or research credit carry-forwards because we believe that it is uncertain that we will have sufficient income from future operations to realize the carry-forwards prior to their expiration. Accordingly, we have established a 100% valuation allowance against the deferred tax asset arising from the carry-forwards.

TABLE OF CONTENTS