GLYCOMIMETICS INC
Form 10-Q
May 02, 2019
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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FORM 10-Q

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(Mark one)

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

For the quarterly period ended March 31, 2019

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 001-36177

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GlycoMimetics, Inc.

(Exact name of registrant as specified in its charter)

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| | |
|---|---|
| Delaware | 06-1686563 |
| (State or Other Jurisdiction of | (I.R.S. Employer |
| Incorporation or Organization) | Identification No.) |
| 9708 Medical Center Drive | |
| Rockville, Maryland | 20850 |
| (Address of principal executive offices) | (Zip Code) |

(240) 243-1201

(Registrant's telephone number, including area code)

N/A

(Former name, former address and former fiscal year, if changed since last report)

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). Yes No

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

Large accelerated filer Accelerated filer Smaller reporting company

Non-accelerated filer Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Securities Exchange Act of 1934). Yes No

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading symbol(s) | Name of each exchange on which registered |
|---|---|---|
| Common Stock, $0.001 par value | GLYC | The Nasdaq Stock Market |

The number of outstanding shares of the registrant's common stock, par value $0.001 per share, as of the close of business on April 30, 2019 was 43,181,169.

GLYCOMIMETICS, INC.

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Part I. FINANCIAL INFORMATION

Item 1. Financial Statements

GLYCOMIMETICS, INC.

Balance Sheets

| | March 31, 2019 (Unaudited) | December 31, 2018 |
|---|---|---|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | $ 195,560,926 | $ 209,917,595 |
| Prepaid expenses and other current assets | 2,828,959 | 2,351,524 |
| Total current assets | 198,389,885 | 212,269,119 |
| Property and equipment, net | 962,241 | 957,226 |
| Prepaid research and development expenses | 1,560,607 | 1,560,607 |
| Deposits | 52,320 | 52,320 |
| Operating lease right-of-use asset | 3,476,452 | — |
| Total assets | $ 204,441,505 | $ 214,839,272 |
| Liabilities & stockholders' equity | | |
| Current liabilities: | | |
| Accounts payable | $ 1,866,937 | $ 2,663,579 |
| Accrued bonuses | 517,361 | 1,727,184 |
| Accrued expenses | 5,182,626 | 4,273,620 |
| Operating lease liabilities | 739,930 | — |
| Deferred rent | — | 98,771 |
| Total current liabilities | 8,306,854 | 8,763,154 |
| Noncurrent operating lease liabilities | 3,341,056 | — |
| Deferred rent, net of current portion | — | 611,623 |
| Total liabilities | 11,647,910 | 9,374,777 |
| Stockholders' equity: | | |
| Preferred stock; $0.001 par value; 5,000,000 shares authorized, no shares issued and outstanding at March 31, 2019 and December 31, 2018 | — | — |
| Common stock; $0.001 par value; 100,000,000 shares authorized, 43,180,169 shares issued and outstanding at March 31, 2019; 100,000,000 shares authorized, 43,160,751 shares issued and outstanding at December 31, 2018 | 43,179 | 43,159 |
| Additional paid-in capital | 407,385,052 | 405,972,075 |
| Accumulated deficit | (214,634,636) | (200,550,739) |
| Total stockholders' equity | 192,793,595 | 205,464,495 |
| Total liabilities and stockholders' equity | $ 204,441,505 | $ 214,839,272 |

The accompanying notes are an integral part of the unaudited financial statements.

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GLYCOMIMETICS, INC.

Unaudited Statements of Operations and Comprehensive Loss

| | Three Months Ended March 31, | |
|---|---|---|
| | 2019 | 2018 |
| Revenue | $ — | $ — |
| Costs and expenses: | | |
| Research and development expense | 11,772,666 | 9,021,423 |
| General and administrative expense | 3,360,448 | 2,855,125 |
| Total costs and expenses | 15,133,114 | 11,876,548 |
| Loss from operations | (15,133,114) | (11,876,548) |
| Interest income | 1,049,217 | 363,704 |
| Net loss and comprehensive loss | $ (14,083,897) | $ (11,512,844) |
| Basic and diluted net loss per common share | $ (0.33) | $ (0.33) |
| Basic and diluted weighted average number of common shares | 43,166,967 | 35,156,090 |

The accompanying notes are an integral part of the unaudited financial statements.

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GLYCOMIMETICS, INC.

Unaudited Statements of Stockholders' Equity

| | Three Months Ended March 31, 2019 | | | | |
|---|---|---|---|---|---|
| | Common Stock Shares | Amount | Additional Paid-In Capital | Accumulated Deficit | Total Stockholders' Equity |
| Balance at December 31, 2018 | 43,160,751 | $ 43,159 | $ 405,972,075 | $ (200,550,739) | $ 205,464,495 |
| Exercise of options | 19,418 | 20 | 30,534 | — | 30,554 |
| Stock-based compensation | — | — | 1,382,443 | — | 1,382,443 |
| Net loss | — | — | — | (14,083,897) | (14,083,897) |
| Balance at March 31, 2019 | 43,180,169 | $ 43,179 | $ 407,385,052 | $ (214,634,636) | $ 192,793,595 |

| | Three Months Ended March 31, 2018 | | | | |
|---|---|---|---|---|---|
| | Common Stock Shares | Amount | Additional Paid-In Capital | Accumulated Deficit | Total Stockholders' Equity |
| Balance at December 31, 2017 | 34,359,799 | $ 34,358 | $ 271,944,173 | $ (152,277,106) | $ 119,701,425 |
| Issuance of common stock, net of issuance costs | 8,050,000 | 8,050 | 128,427,950 | — | 128,436,000 |
| Exercise of options and warrants | 80,311 | 81 | 298,708 | — | 298,789 |
| Stock-based compensation | — | — | 1,115,830 | — | 1,115,830 |
| Net loss | — | — | — | (11,512,844) | (11,512,844) |
| Balance at March 31, 2018 | 42,490,110 | 42,489 | 401,786,661 | (163,789,950) | 238,039,200 |

The accompanying notes are an integral part of the unaudited financial statements.

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GLYCOMIMETICS, INC.

Unaudited Statements of Cash Flows

| | Three Months Ended March 31, | |
|---|---|---|
| | 2019 | 2018 |
| Operating activities | | |
| Net loss | $ (14,083,897) | $ (11,512,844) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation | 70,441 | 68,757 |
| Amortization of operating lease right-of-use asset | 149,686 | — |
| Stock-based compensation expense | 1,382,443 | 1,115,830 |
| Changes in assets and liabilities: | | |
| Prepaid expenses and other current assets | (561,897) | (182,401) |
| Accounts payable | (832,560) | 1,206,896 |
| Accrued expenses and bonuses | (300,817) | (887,737) |
| Operating lease liabilities | (171,084) | (17,325) |
| Net cash used in operating activities | (14,347,685) | (10,208,824) |
| | | |
| Investing activities | | |
| Purchases of property and equipment | (39,538) | (16,618) |
| Net cash used in investing activities | (39,538) | (16,618) |
| | | |
| Financing activities | | |
| Proceeds from issuance of common stock, net of issuance costs | — | 128,634,000 |
| Proceeds from exercise of stock options and warrants | 30,554 | 298,789 |
| Net cash provided by financing activities | 30,554 | 128,932,789 |
| Net change in cash and cash equivalents | (14,356,669) | 118,707,347 |
| Cash and cash equivalents, beginning of period | 209,917,595 | 123,924,738 |
| Cash and cash equivalents, end of period | $ 195,560,926 | $ 242,632,085 |
| | | |
| Non-cash investing and financing activities | | |
| Property acquisition costs included in accrued expenses | $ 35,918 | $ — |
| Issuance costs associated with financing included in accrued expenses | $ — | $ 198,000 |

The accompanying notes are an integral part of the unaudited financial statements.

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GLYCOMIMETICS, INC.

Notes to Unaudited Financial Statements

1. Description of the Business

GlycoMimetics, Inc. (the Company), a Delaware corporation headquartered in Rockville, Maryland, was incorporated in April 2003. The Company is a clinical-stage biotechnology company focused on the discovery and development of novel glycomimetic drugs to address unmet medical needs resulting from diseases in which carbohydrate biology plays a key role. Glycomimetics are molecules that mimic the structure of carbohydrates involved in important biological processes. Using its expertise in carbohydrate chemistry and knowledge of carbohydrate biology, the Company is developing a pipeline of proprietary glycomimetics that inhibit disease-related functions of carbohydrates, such as the roles they play in inflammation, cancer and infection.

The Company’s executive personnel have devoted substantially all of their time to date to the planning and organization of the Company, the process of hiring scientists and other personnel, initiating and overseeing research and development programs, including planned and ongoing clinical trials, and securing adequate capital for anticipated growth and operations. The Company has not commercialized any of its drug candidates or commenced commercial operations. The Company is subject to a number of risks similar to those of other companies in similar development stages, including dependence on key individuals, the need to develop commercially viable drugs, the need to successfully compete with other companies, many of whom are larger and better capitalized, and the need to obtain adequate additional financing to fund the development of its drug candidates. The Company has incurred significant operating losses since inception and has relied on its ability to fund its operations through private and public equity financings, and management expects operating losses and negative operating cash flows to continue for the foreseeable future. As the Company continues to incur losses, profitability will be dependent upon the successful development, approval and commercialization of its drug candidates and achieving a level of revenues adequate to support the Company’s cost structure. The Company may never achieve profitability, and unless and until it does, the Company will continue to need to raise additional capital. The Company believes that its currently available funds will be sufficient to fund the Company’s operations through at least 12 months from the date of the filing of this Quarterly Report. Management intends to fund future operations through additional public or private equity or debt offerings and potential future milestone and royalty payments from Pfizer, as described in Note 9, “Research and License Agreements,” and may seek additional capital through arrangements with strategic partners or from other sources.

2. Significant Accounting Policies

Basis of Accounting

The accompanying financial statements were prepared based on the accrual method of accounting in accordance with U.S. generally accepted accounting principles (GAAP).

Unaudited Financial Statements

The accompanying balance sheet as of March 31, 2019, statements of operations and comprehensive loss, statements of stockholders' equity and statements of cash flows for the three months ended March 31, 2019 and 2018 are unaudited. These unaudited financial statements have been prepared in accordance with the rules and regulations of the United States Securities and Exchange Commission (the SEC) for interim financial information. Accordingly, they do not include all of the information and footnotes required by GAAP for complete annual financial statements. These financial statements should be read in conjunction with the audited financial statements and the accompanying notes for the year ended December 31, 2018 contained in the Company's Annual Report on Form 10-K filed with the SEC on March 6, 2019. The unaudited interim financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments (consisting of normal recurring adjustments) necessary to state fairly the Company's financial position as of March 31, 2019, its results of operations for the three months ended March 31, 2019 and 2018, changes in its stockholders' equity for the three months ended March 31, 2019 and 2018 and its cash flows for the three months ended March 31, 2019 and 2018. The December 31, 2018 balance sheet included herein was derived from audited financial statements, but does not include all disclosures including notes required by GAAP for complete annual financial statements. The financial data and other information disclosed in these

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notes to the financial statements related to the three months ended March 31, 2019 and 2018 are unaudited. Interim results are not necessarily indicative of results for an entire year or for any future period.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Although actual results could differ from those estimates, management does not believe that such differences would be material.

Fair Value Measurements

The Company had no assets or liabilities that were measured using quoted prices for similar assets and liabilities or significant unobservable inputs (Level 2 and Level 3 assets and liabilities, respectively) as of March 31, 2019 and December 31, 2018. The carrying value of cash held in money market funds of $193.6 million and $207.9 million as of March 31, 2019 and December 31, 2018, respectively, is included in cash and cash equivalents and approximates market values based on quoted market prices (Level 1 inputs).

Concentration of Credit Risk

Credit risk represents the risk that the Company would incur a loss if counterparties failed to perform pursuant to the terms of their agreements. Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents. Cash and cash equivalents consist of money market funds with major financial institutions in the United States. These funds may be redeemed upon demand and, therefore, bear minimal risk. The Company does not anticipate any losses on such balances.

Revenue Recognition

The Company applies Accounting Standards Codification, or ASC, Topic 606, Revenue from Contracts with Customers (Topic 606), to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under Topic 606, an entity

recognizes revenue when its customer obtains control of promised goods or services in an amount that reflects the consideration which the entity expects to receive in exchange for those goods and services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with the customer(s); (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods and services it transfers to the customer. At contract inception, the Company assesses the goods or services promised within each contract that falls under the scope of Topic 606, determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The Company enters into licensing agreements which are within the scope of Topic 606, under which it licenses certain of its drug candidates' rights to third parties. The terms of these arrangements typically include payment of one or more of the following: non-refundable, up-front license fees; development, regulatory and commercial milestone payments; and royalties on net sales of the licensed product, if and when earned.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligation under each of its agreements, the Company performs the five steps under Topic 606 described above. As part of the accounting for these arrangements, the Company must develop assumptions that require judgment to determine the stand-alone selling price, which may include forecasted revenues, development timelines, reimbursement of personnel costs, discount rates and probabilities of technical and regulatory success.

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Licensing of Intellectual Property: If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period, and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone Payments: At the inception of each arrangement that includes development milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal will not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license, collaboration and other revenues and earnings in their period of adjustment.

Royalties: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and for which the license is deemed to be the predominant item to which royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue from its license agreements.

The Company entered into a collaborative research and development agreement with Pfizer Inc. (Pfizer) in 2011. The agreement is in the form of a license agreement (the Pfizer Agreement). The Pfizer Agreement calls for a non-refundable up-front payment and milestone payments upon achieving significant milestone events. The Pfizer Agreement also contemplates royalty payments on future sales of an approved product. There are no performance, cancellation, termination or refund provisions in the Pfizer Agreement that contain material financial consequences to the Company. For a complete discussion of the Company's accounting for the Pfizer Agreement, see Note 9, "Research and License Agreements."

Accrued Liabilities

The Company is required to estimate accrued liabilities as part of the process of preparing its financial statements. The estimation of accrued liabilities involves identifying services that have been performed on the Company's behalf, and then estimating the level of service performed and the associated cost incurred for such services as of each balance sheet date. Accrued liabilities include professional service fees, such as for lawyers and accountants, contract service fees, such as those under contracts with clinical monitors, data management organizations and investigators in conjunction with clinical trials, and fees to contract manufacturers in conjunction with the production of clinical materials. Pursuant to the Company's assessment of the services that have been performed, the Company recognizes these expenses as the services are provided. Such assessments include: (i) an evaluation by the project manager of the work that has been completed during the period; (ii) measurement of progress prepared internally and/or provided by the third-party service provider; (iii) analyses of data that justify the progress; and (iv) the Company's judgment.

Research and Development Costs

Except for payments made in advance of services, research and development costs are expensed as incurred. For payments made in advance, the Company recognizes research and development expense as the services are rendered. Research and development costs primarily consist of salaries and related expenses for personnel, laboratory supplies and raw materials, sponsored research, depreciation of laboratory facilities and leasehold improvements, and utilities costs

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related to research space. Other research and development expenses include fees paid to consultants and outside service providers including clinical research organizations and clinical manufacturing organizations.

Stock-Based Compensation

Stock-based payments are accounted for in accordance with the provisions of ASC 718, Compensation—Stock Compensation. The fair value of stock-based payments is estimated, on the date of grant, using the Black-Scholes-Merton model. The resulting fair value is recognized ratably over the requisite service period, which is generally the vesting period of the option.

The Company has elected to use the Black-Scholes-Merton option pricing model to value any options granted. The Company will reconsider use of the Black-Scholes-Merton model if additional information becomes available in the future that indicates another model would be more appropriate or if grants issued in future periods have characteristics that prevent their value from being reasonably estimated using this model.

A discussion of management’s methodology for developing some of the assumptions used in the valuation model follows:

Expected Dividend Yield—The Company has never declared or paid dividends and has no plans to do so in the foreseeable future.

Expected Volatility—Volatility is a measure of the amount by which a financial variable such as share price has fluctuated (historical volatility) or is expected to fluctuate (expected volatility) during a period. The Company utilizes the historical volatilities of a peer group (e.g., several public entities of similar size, complexity, and stage of development), along with the Company’s historical volatility since its initial public offering, to determine its expected volatility.

Risk-Free Interest Rate—This is the U.S. Treasury rate for the week of each option grant during the year, having a term that most closely resembles the expected life of the option.

Expected Term—This is a period of time that the options granted are expected to remain unexercised. Options granted have a maximum term of 10 years. The Company estimates the expected life of the option term to be 6.25 years. The Company uses a simplified method to calculate the average expected term.

Expected Forfeiture Rate—The Company accounts for forfeitures as they occur and does not make an estimate of expected forfeitures at the time of grant.

Net Loss Per Common Share

Basic net loss per common share is determined by dividing net loss by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. Diluted net loss per share is computed by dividing net loss by the weighted-average number of common stock equivalents outstanding for the period. The treasury stock method is used to determine the dilutive effect of the Company's stock options, restricted stock units and warrants.

The following potentially dilutive securities outstanding, at March 31, have been excluded from the computation of diluted weighted average common shares outstanding, as they would be anti-dilutive:

| | Three Months Ended March 31, | |
|---|---|---|
| | 2019 | 2018 |
| Warrants | — | 553,868 |
| Stock options and restricted stock units | 4,836,170 | 3,952,792 |

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Comprehensive Loss

Comprehensive loss comprises net loss and other changes in equity that are excluded from net loss. For the three months ended March 31, 2019 and 2018, the Company's net loss equaled comprehensive net loss and, accordingly, no additional disclosure is presented.

Recently Issued Accounting Standards

Adopted Accounting Standards

In February 2016, the Financial Accounting Standards Board (FASB) issued ASU No. 2016-02, Leases (Topic 842), which generally requires all leases, including operating leases, to be recognized in the statement of financial position as right-of-use assets and lease liabilities by lessees. The provisions of ASU No. 2016-02 were applied using a modified retrospective approach and were adopted by the Company effective January 1, 2019. The Company elected the transition option provided under ASU No. 2018-11, which did not require adjustments to comparative periods or modified disclosures in those comparative periods. The Company elected the practical expedient as an accounting policy election by class of underlying asset to account for each separate lease component of a contract and its associated non-lease component as a single lease component. This practical expedient was applied to all underlying asset classes. Upon adoption of the standard, the Company recorded right-of-use assets and related lease liabilities for operating leases of approximately $3.6 million and $4.3 million, respectively, as of January 1, 2019. The difference between these amounts is comprised of adjustments related to unamortized balances of deferred rent, lease incentives, and prepaid rent existing as of the effective date. The adoption of the standard did not materially affect the Company's net earnings or the statement of cash flows. For further discussion on the adoption of this standard, see Note 6, "Leases."

In June 2018, the FASB issued ASU No. 2018-07, Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-based Payment Accounting, to simplify the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. The Company adopted this ASU as of January 1, 2019. Upon transition, the Company measured nonemployee awards at fair value as of the adoption date. The adoption of the standard did not materially affect operating results, cash flows or financial position.

In August 2018, the U.S. Securities and Exchange Commission (SEC) adopted the final rule under SEC Release No. 33-10532, Disclosure Update and Simplification. This final rule amends certain disclosure requirements that are redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expand the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the balance sheet must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of comprehensive income is required to be filed. This final rule is effective for the Company for all filings made on or after November 5, 2018. The SEC staff clarified that the first presentation of the changes in shareholders' equity may be included in the first Form 10-Q for the quarter that begins after the effective date of the amendments. Effective with the adoption of the rule, the Company included a separate statement of stockholders' equity in the financial statements for the three months ended March 31, 2019 and 2018.

Accounting Standards Not Yet Adopted

In November 2018, the FASB issued ASU No. 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606. The amendment clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account. In those situations, all the guidance in Topic 606 should be applied, including recognition, measurement, presentation and disclosure requirements. The amendment also adds unit-of-account guidance in Topic 808 to align with the guidance in Topic 606 (that is, a distinct good or service) when an entity is assessing whether the collaborative arrangement or a part of the arrangement is within the scope of Topic 606. Lastly, the amendment requires that in a transaction with a collaborative arrangement participant that is not directly related to sales to third parties, presenting the transaction together with revenue recognized under Topic 606 is precluded if the collaborative arrangement participant is not a customer. For public business entities, the amendments are effective

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for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. The Company is currently evaluating these clarifications in the accounting and presentation for its collaborative arrangements within the scope of Topic 808 but does not expect it will have any impact.

With the exception of the new standards discussed above, there have been no new accounting pronouncements that have significance, or potential significance, to the Company's financial statements.

3. Prepaid Expenses and Other Current Assets

The following is a summary of the Company's prepaid expenses and other current assets:

| | March 31, 2019 | December 31, 2018 |
|---|---|---|
| Prepaid research and development expenses | $ 2,122,098 | $ 1,608,768 |
| Other prepaid expenses | 352,760 | 329,634 |
| Other receivables | 354,101 | 413,122 |
| Prepaid expenses and other current assets | $ 2,828,959 | $ 2,351,524 |

4. Property and Equipment

Property and equipment, net consists of the following:

| | March 31, 2019 | December 31, 2018 |
|---|---|---|
| Furniture and fixtures | $ 334,300 | $ 334,300 |
| Laboratory equipment | 1,392,166 | 1,389,036 |
| Office equipment | 11,085 | 11,085 |
| Computer equipment | 269,690 | 233,282 |
| Leasehold improvements | 609,083 | 573,165 |
| Property and equipment | 2,616,324 | 2,540,868 |

| | | |
|---|---|---|
| Less accumulated depreciation | (1,654,083) | (1,583,642) |
| Property and equipment, net | $ 962,241 | $ 957,226 |

Depreciation expense was $70,441 and $68,757 for the three months ended March 31, 2019 and 2018, respectively.

5. Accrued Expenses

The following is a summary of the Company's accrued expenses:

| | March 31, 2019 | December 31, 2018 |
|---|---|---|
| Accrued research and development expenses | $ 3,967,216 | $ 3,483,741 |
| Accrued consulting and other professional fees | 457,877 | 140,397 |
| Accrued employee benefits | 440,136 | 385,789 |
| Other accrued expenses | 317,397 | 263,693 |
| Accrued expenses | $ 5,182,626 | $ 4,273,620 |

6. Leases

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the circumstances present. The Company determines a lease exists if the contract conveys the right to control an identified asset for a period of time in exchange for consideration. Control is considered to exist when the lessee has the right to obtain substantially all of the economic benefits from the use of an identified asset as well as direct the right to

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use of that asset. Leases with a term greater than one year are recognized on the balance sheet as right-of-use assets, lease liabilities and, if applicable, long-term lease liabilities. The Company has elected not to recognize on the balance sheet leases with terms of one year or less. If a contract is considered to be a lease, the Company recognizes a lease liability based on the present value of the future lease payments over the expected lease term, with an offsetting entry to recognize a right-of-use asset.

The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company utilizes the appropriate incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a term similar to the term of the lease for which the rate is estimated. Certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or incentives received.

The components of a lease should be split into three categories: lease components (e.g., land, building, etc.), non-lease components (e.g., common area maintenance, maintenance, consumables, etc.), and non-components (e.g., property taxes, insurance, etc.). Then the fixed and in-substance fixed contract consideration (including any related to non-components) must be allocated based on fair values to the lease components and non-lease components. Although separation of lease and non-lease components is required, certain practical expedients are available to entities. Entities electing the practical expedient would not separate lease and non-lease components. Rather, they would account for each lease component and the related non-lease component together as a single component. The Company’s facilities operating leases have lease and non-lease components. The Company has elected to use the practical expedient and account for each lease component and related non-lease component as one single component. The lease component results in a right-of-use asset being recorded on the balance sheet and amortized as lease expense on a straight-line basis.

The Company leases office and research space in Rockville, Maryland under an operating lease with a term from June 15, 2015 through October 31, 2023 (as amended to date, the Lease) that is subject to annual rent increases. The Company has the right to sublease or assign all or a portion of the premises, subject to the conditions set forth in the Lease. The Lease may be terminated early by either the landlord or the Company in certain circumstances. In connection with the Lease, the Company received rent abatement as a lease incentive in the initial year of the Lease.

In March 2016, the Company amended the Lease (the Lease Amendment) to lease additional space as of June 1, 2016. In May 2016, the Company also paid a security deposit of $52,320 to be held until the expiration or termination of the Company’s obligations under the Lease. The term of the Lease Amendment for the additional space continues through October 31, 2023, the same date as for the premises originally leased under the Lease, subject to the Company’s renewal option set forth in the Lease. The Company’s one-time option to terminate the Lease effective as of October 31, 2020 also applies to the additional space.

The Company identified and applied the following significant assumptions in recognizing the right-of-use asset and corresponding liability for the Lease and Lease Amendment:

- Lease term – The lease term includes both the noncancelable period and, when applicable, cancelable option periods where failure to exercise such option would result in an economic penalty. The Company's renewal option to extend is not reasonably certain of being exercised as of March 31, 2019.

- Incremental borrowing rate – As the Company's lease does not provide an implicit rate, the Company used an incremental borrowing rate, or IBR, which is the rate incurred to borrow on a collateralized basis over a term similar to the term of the lease for which the rate is estimated. The Company determined the IBR based on an estimated rate that considered the Company's credit risk in the United States for a collateralized borrowing and lease term similar to the Lease.

With the adoption of ASU 2016-02 on January 1, 2019, the Company recorded a right-of use asset of $3.6 million and corresponding lease liability of $4.3 million by calculating the present value of lease payments, discounted at 8.01%, the Company's IBR, over the expected term of 4.8 years. As of March 31, 2019 the weighted average remaining lease term was 4.6 years. There were no additional operating leases entered into during the quarter ended March 31, 2019.

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The components of lease expense and related cash flows were as follows:

| | Three Months Ended March 31, 2019 |
|---|---|
| Operating lease cost | $ 231,989 |
| Variable lease cost | 91,758 |
| Total operating lease cost | $ 323,747 |
| | |
| Cash paid for amounts included in the measurement of lease liabilities: | |
| Operating cash flows from operating leases | $ 253,387 |

Maturities of lease liability due under these lease agreements as of March 31, 2019 are as follows:

| | Operating Lease Obligation |
|---|---|
| April 1, 2019 - December 31, 2019 | $ 773,521 |
| 2020 | 1,052,581 |
| 2021 | 1,078,895 |
| 2022 | 1,105,867 |
| 2023 | 846,830 |
| Thereafter | — |
| Total | 4,857,694 |
| Present value adjustment | (776,708) |
| Present value of lease payments | $ 4,080,986 |

7. Stockholders’ Equity

At-The-Market Sales Facility

On September 28, 2017, the Company entered into an at-the-market sales agreement (the "September 2017 Sales Agreement") with Cowen and Company, LLC to sell up to $100.0 million of the Company's common stock registered under a shelf registration statement filed with the U.S. Securities and Exchange Commission in September 2017. As of March 31, 2019, $80.0 million remained available to be sold under the terms of the September 2017 Sales Agreement. There were no shares sold under the September 2017 Sales Agreement during the three months ended March 31, 2019 and March 31, 2018.

2003 Stock Incentive Plan

The 2003 Stock Incentive Plan (the 2003 Plan) provided for the grant of incentives and nonqualified stock options and restricted stock awards. The exercise price for incentive stock options must be at least equal to the fair value of the common stock on the grant date. Unless otherwise stated in a stock option agreement, 25% of the shares subject to an option grant will vest upon the first anniversary of the vesting start date and thereafter at the rate of one forty-eighth of the option shares per month as of the first day of each month after the first anniversary. Upon termination of employment by reasons other than death, cause, or disability, any vested options shall terminate 60 days after the termination date. Stock options terminate 10 years from the date of grant. The 2003 Plan expired on May 21, 2013.

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A summary of the Company's stock option activity under the 2003 Plan for the three months ended March 31, 2019 is as follows:

| | Outstanding Options | Weighted-Average Exercise Price | Weighted-Average Remaining Contractual Term (Years) | Aggregate Intrinsic Value (In thousands) |
|---|---|---|---|---|
| Outstanding as of December 31, 2018 | 667,080 | $ 1.24 | 2.2 | |
| Options exercised | (11,000) | 1.12 | | |
| Options forfeited | — | — | | |
| Outstanding, Vested and Exercisable as of March 31, 2019 | 656,080 | 1.25 | 1.9 | $ 7,358 |

As of March 31, 2019, outstanding options under the 2003 Plan were fully expensed and all shares underlying outstanding options were fully vested. Total intrinsic value of the options exercised during the three months ended March 31, 2019 and 2018 was $129,250 and $407,776, respectively, and total cash received for options exercised was $12,320 and $26,572 during the three months ended March 31, 2019 and 2018, respectively.

2013 Equity Incentive Plan

The Company's board of directors adopted, and its stockholders approved, its 2013 Equity Incentive Plan (the 2013 Plan) effective on January 9, 2014. The 2013 Plan provides for the grant of incentive stock options within the meaning of Section 422 of the Internal Revenue Code to the Company's employees and its parent and subsidiary corporations' employees, and for the grant of nonstatutory stock options, restricted stock awards, restricted stock unit awards, stock appreciation rights, performance stock awards and other forms of stock compensation to its employees, including officers, consultants and directors. The 2013 Plan also provides for the grant of performance cash awards to the Company's employees, consultants and directors. Unless otherwise stated in a stock option agreement, 25% of the shares subject to an option grant will typically vest upon the first anniversary of the vesting start date and thereafter at the rate of one forty-eighth of the option shares per month as of the first day of each month after the first anniversary. Upon termination of employment by reasons other than death, cause, or disability, any vested options will terminate 90 days after the termination date, unless otherwise set forth in a stock option agreement. Stock options generally terminate 10 years from the date of grant.

Authorized Shares

The maximum number of shares of common stock that initially could be issued under the 2013 Plan was 1,000,000 shares, plus any shares subject to stock options or similar awards granted under the 2003 Plan that expire or terminate without having been exercised in full or are forfeited or repurchased by the Company. The number of

shares of common stock reserved for issuance under the 2013 Plan automatically increases on January 1 of each year until January 1, 2023, by 3% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares as may be determined by the Company's board of directors. The maximum number of shares that may be issued pursuant to exercise of incentive stock options under the 2013 Plan is 20,000,000 shares. As of January 1, 2019, the number of shares of common stock that may be issued under the 2013 Plan was automatically increased by 1,294,822 shares, representing 3% of the total number of shares of common stock outstanding on December 31, 2018, increasing the number of shares of common stock available for issuance under the 2013 Plan to 5,162,816 shares.

Shares issued under the 2013 Plan may be authorized but unissued or reacquired shares of common stock. Shares subject to stock awards granted under the 2013 Plan that expire or terminate without being exercised in full, or that are paid out in cash rather than in shares, will not reduce the number of shares available for issuance under the 2013 Plan. Additionally, shares issued pursuant to stock awards under the 2013 Plan that the Company repurchases or that are forfeited, as well as shares reacquired by the Company as consideration for the exercise or purchase price of a stock award or to satisfy tax withholding obligations related to a stock award, will become available for future grant under the 2013 Plan.

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A summary of the Company's stock option activity under the 2013 Plan for the three months ended March 31, 2019 is as follows:

| | Outstanding Options | Weighted-Average Exercise Price | Weighted-Average Remaining Contractual Term (Years) | Aggregate Intrinsic Value (In thousands) |
|---|---|---|---|---|
| Outstanding as of December 31, 2018 | 3,265,254 | $ 8.39 | 7.1 | |
| Options granted | 922,596 | 10.65 | | |
| Options exercised | (3,585) | 5.09 | | |
| Options forfeited | (4,175) | 16.24 | | |
| Outstanding as of March 31, 2019 | 4,180,090 | 10.33 | 7.5 | $ 14,618 |
| Vested or expected to vest as of March 31, 2019 | 4,180,090 | 10.33 | 7.5 | $ 14,618 |
| Exercisable as of March 31, 2019 | 2,283,631 | 8.60 | 6.2 | $ 10,545 |

The weighted-average fair value of the options granted during the three months ended March 31, 2019 and 2018 was $7.00 per share and $13.70 per share, respectively, applying the Black-Scholes-Merton option pricing model utilizing the following weighted-average assumptions:

| | Three Months Ended March 31, | |
|---|---|---|
| | 2019 | 2018 |
| Expected term | 6.25 years | 6.25 years |
| Expected volatility | 71.34% | 73.89% |
| Risk-free interest rate | 2.62% | 2.42% |
| Expected dividend yield | 0% | 0% |

As of March 31, 2019, there was $14,142,362 of total unrecognized compensation expense related to unvested options under the 2013 Plan that will be recognized over a weighted-average period of approximately 3.1 years. Total intrinsic value of the options exercised during the three months ended March 31, 2019 and 2018 was $23,176 and $535,449, respectively, and total cash received for options exercised was $18,234 and $272,217 during the three months ended March 31, 2019 and 2018, respectively. The total fair value of shares underlying options which vested in the three months ended March 31, 2019 and 2018 was $2,724,218 and $1,193,174, respectively.

A restricted stock unit (RSU) is a stock award that entitles the holder to receive shares of the Company's common stock as the award vests. The fair value of each RSU is based on the closing price of the Company's common stock on the date of grant. The Company has granted RSUs with service conditions (service RSUs) that vest in three equal annual installments provided that the employee remains employed with the Company at each installment date. As of March 31, 2019, outstanding RSUs under the 2013 Plan were fully expensed and all shares were fully vested.

The following is a summary of RSU activity under the 2013 Plan for the three months ended March 31, 2019:

| | Number of Shares Underlying RSUs | Weighted-Average Grant Date Fair Value |
|---|---|---|
| Unvested at December 31, 2018 | 4,833 | $ 4.61 |
| Granted | — | — |
| Forfeited | — | — |
| Vested | 4,833 | 4.61 |
| Unvested at March 31, 2019 | — | — |

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Stock-based compensation expense was classified on the statements of operations as follows for the three months ended March 31, 2019 and 2018:

| | Three Months Ended March 31, | |
|---|---|---|
| | 2019 | 2018 |
| Research and development expense | $ 507,822 | $ 425,209 |
| General and administrative expense | 874,621 | 690,621 |
| Total stock-based compensation expense | $ 1,382,443 | $ 1,115,830 |

8. Income Taxes

The Company has not recorded any tax provision or benefit for the three months ended March 31, 2019 and 2018. The Company has provided a valuation allowance for the full amount of its net deferred tax assets since realization of any future benefit from deductible temporary differences, net operating loss carryforwards and research and development credits is not more-likely-than-not to be realized at March 31, 2019 and December 31, 2018.

9. Research and License Agreements

In 2011, the Company and Pfizer entered into the Pfizer Agreement that provides Pfizer an exclusive worldwide license to rivipansel for vaso-occlusive crisis associated with sickle cell disease and for other diseases for which the drug candidate may be developed. The Company was responsible for completion of the Phase 2 clinical trial, after which Pfizer assumed all further development and commercialization responsibilities. Upon execution of the Pfizer Agreement, the Company received an up-front payment of $22.5 million. The Pfizer Agreement also provides for potential milestone payments of up to $115.0 million upon the achievement of specified development milestones, including the dosing of the first patients in Phase 3 clinical trials for up to two indications and the first commercial sale of a licensed product in the United States and selected European countries for up to two indications; potential

milestone payments of up to $70.0 million upon the achievement of specified regulatory milestones, including the acceptance of our filings for regulatory approval by regulatory authorities in the United States and Europe for up to two indications; and potential milestone payments of up to $135.0 million upon the achievement of specified levels of annual net sales of licensed products. Pfizer has the right to terminate the Pfizer Agreement by giving prior written notice.

The Company assessed this arrangement in accordance with Topic 606 and concluded that the contract counterparty, Pfizer, is a customer. The Company identified the following performance obligations under the contract: (1) an exclusive worldwide license to rivipansel for vaso-occlusive crisis associated with sickle cell disease and for other diseases for which the drug candidate may be developed; and (2) research and development (R&D) services to develop the rivipansel compound for commercial use related to the Phase 2 clinical trial and delivery of data to Pfizer. Based on the Company's assessment, the Company determined that the rivipansel license and R&D services are not distinct and are therefore considered as one combined performance obligation. In addition to the rivipansel license and R&D services, management also considered whether the Company's participation in a Joint Steering Committee (JSC) constituted a promise. The JSC was formed solely for communication purposes between Pfizer and the Company relating to Pfizer's progress in further developing rivipansel for commercial use. The Company's involvement in the JSC is limited to attending the JSC meetings on a semi-annual basis to receive progress updates from Pfizer; Pfizer is responsible for calling and organizing the meetings. Given the minimal level of involvement by the Company, participation in the JSC is not considered a significant aspect of the arrangement and the related costs, such as employee time, are not material. Therefore, management views the Company's participation in the JSC as administrative only and did not further evaluate its participation in the JSC in identifying the performance obligations in the Pfizer Agreement.

Under the Pfizer Agreement, in order to evaluate the appropriate transaction price, the Company determined that the up-front amount constituted the entirety of the consideration to be included in the transaction price. The transaction price of the up-front fee is equal to the $22.5 million received. The fixed up-front consideration was recognized under ASC 606 based on when control of the combined performance obligation was transferred to the customer, which corresponded with the service period (through March 2013). None of the clinical or regulatory milestones have been included in the transaction price, as all milestone amounts were fully constrained. Event-driven milestones are a form of variable consideration as the payments are variable based on the occurrence of future events. As part of its evaluation of

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the constraint, the Company considered numerous factors, including that receipt of the milestones is outside the control of the Company and is contingent upon success in future clinical trials and the licensee's efforts. Recognition of event-driven milestones should be recognized when the variable consideration is no longer constrained. Future event-driven milestones will be recognized when the constraint no longer applies. The Company received a $15.0 million non-refundable milestone payment in May 2014 and an additional non-refundable milestone payment of $20.0 million in June 2015. The Company did not recognize any revenue under the Pfizer Agreement during the three months ended March 31, 2019 or 2018.

Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur as they were determined to relate predominantly to the license granted to Pfizer and therefore have also been excluded from the transaction price. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur. In evaluating the Pfizer Agreement, the Company considered that there were no significant financing components identified, no non-cash consideration was paid by Pfizer and no consideration was paid by the Company to Pfizer as part of the arrangement.

The Company has entered into a research services agreement (the Research Agreement) with the University of Basel (the University) for biological evaluation of selectin antagonists. While the scope of work under the Research Agreement with the University ended in 2017, certain patents covering the rivipansel compound are subject to provisions of the Research Agreement. Under the terms of the Research Agreement, the Company owes to the University 10% of all milestone and royalty payments received from Pfizer with respect to rivipansel. There were no milestone payments due to the University for the three months ended March 31, 2019 or 2018.

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

Certain statements contained in this Quarterly Report on Form 10-Q may constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The words or phrases "would be," "will allow," "intends to," "will likely result," "are expected to," "will continue," "is anticipated," "estimate," "project," or similar expressions, or the negative of such words or phrases, are intended to identify "forward-looking statements." We have based these forward-looking statements on our current expectations and projections about future events. Because such statements include risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to these differences include those below and elsewhere in this Quarterly Report on Form 10-Q, our Annual Report on Form 10-K, particularly in Part I – Item 1A, "Risk Factors," and our other filings with the Securities and Exchange Commission. Statements made herein are as of the date of the filing of this Form 10-Q with the Securities and Exchange Commission and should not be relied upon as of any subsequent date. Unless otherwise required by applicable law, we do not undertake, and we specifically disclaim, any obligation to update any forward-looking statements to reflect occurrences, developments, unanticipated events or circumstances after the date of such statement.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited financial statements and related notes that appear in Item 1 of this Quarterly Report on Form 10-Q and with our audited financial statements and related notes for the year ended December 31, 2018, which are included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 6, 2019.

Overview

We are a clinical-stage biotechnology company focused on the discovery and development of novel glycomimetic drugs to address unmet medical needs resulting from diseases in which carbohydrate biology plays a key role. Glycomimetics are molecules that mimic the structure of carbohydrates involved in important biological processes. Our proprietary glycomimetics platform is based on our expertise in carbohydrate chemistry and our understanding of the role carbohydrates play in key biological processes. Using this expertise and understanding, we are developing a pipeline of proprietary glycomimetics designed to inhibit disease-related functions of carbohydrates, such as the roles they play in inflammation, cancer and infection. We believe this represents an innovative approach to drug discovery to treat a wide range of diseases.

Most human proteins are modified by the addition of complex carbohydrates to the surface of the proteins. The addition of these carbohydrate structures affects the functions of these proteins and their interactions with other molecules. Our initial research and development efforts have focused on drug candidates targeting selectins, which are proteins that serve as adhesion molecules and bind to carbohydrates that are involved in the inflammatory component

and progression of a wide range of diseases, including hematologic disorders, cancer and cardiovascular disease. Inhibiting specific carbohydrates from binding to selectins has long been viewed as a potentially attractive approach for therapeutic intervention. The ability to successfully develop drug-like compounds that inhibit binding with selectins, known as selectin antagonists, has historically been limited by the complexities of carbohydrate chemistry. We believe our expertise in carbohydrate chemistry enables us to design selectin antagonists and other glycomimetics that inhibit the disease-related functions of certain carbohydrates in order to develop novel drug candidates to address orphan diseases with high unmet medical needs.

We are focusing our initial efforts on drug candidates for rare diseases that we believe will qualify for orphan drug designation. Our first drug candidate, rivipansel, is a pan-selectin antagonist being developed for the treatment of vaso-occlusive crisis, a debilitating and painful condition that occurs periodically throughout the life of a person with sickle cell disease. We have entered into an agreement with Pfizer Inc., or Pfizer, for the further development and potential commercialization of rivipansel worldwide. Rivipansel has received fast track designation from the U.S. Food and Drug Administration, or FDA, as well as orphan drug designation from the FDA in the United States and from the European Medicines Agency, or EMA, in the European Union. Since the completion of our Phase 2 clinical trial of rivipansel in 2013, Pfizer has been responsible for the further clinical development, regulatory approval and potential commercialization of rivipansel. Pfizer enrolled the first patient in a Phase 3 clinical trial in June 2015, and we have been

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notified by Pfizer that enrollment is near completion and Pfizer expects to have top-line data from the trial later in 2019. We believe the clinical progress of rivipansel provides evidence of the significant potential of our lead program and our proprietary glycomimetics platform.

Building on our experience with rivipansel, we are developing a pipeline of other glycomimetic drug candidates. Our second glycomimetic drug candidate, uproleselan, is a specific E-selectin inhibitor, which we are developing to be used in combination with chemotherapy to treat patients with acute myeloid leukemia, or AML, a life-threatening hematologic cancer, and potentially other hematologic cancers as well. We have completed an initial Phase 1 trial in healthy volunteers for uproleselan, and in May 2017 we completed enrollment in a Phase 1/2 clinical trial in defined populations of patients with AML. In December 2018, at the annual meeting of the American Society of Hematology, or ASH, we presented clinical data from this Phase 1/2 clinical trial that showed high remission rates and suggested a favorable safety, pharmacokinetic, or PK, and biomarker profile for uproleselan.

In March 2018, we announced our design for a randomized, double-blind, placebo-controlled Phase 3 clinical trial to evaluate uproleselan in individuals with relapsed/refractory AML, which design is aligned with guidance received from the FDA. Based on consultations with the FDA, the single pivotal trial is planned to enroll approximately 380 adult patients with relapsed or refractory AML at centers in the United States, Canada, Europe and Australia. Enrollment began in the fourth quarter of 2018. The primary efficacy endpoint will be overall survival; importantly, the FDA has advised us that data on overall survival will not need to be censored for transplant in the primary efficacy analysis, meaning that patients who proceed to transplant will continue to be included as part of the survival analysis. All patients will be treated with standard chemotherapy of either MEC (mitoxantrone, etoposide and cytarabine) or FAI (fludarabine, cytarabine and idarubicin), with approximately one-half of the patients randomized to receive uproleselan in addition to chemotherapy. Patients receiving uproleselan will be dosed for one day prior to initiation of chemotherapy, twice a day through the chemotherapy regimen, and then for two days after the end of chemotherapy, which was the same regimen as in the Phase 1/2 trial. The dose regimen will be fixed, rather than weight-based, which we believe will simplify administration. We plan to offer up to three cycles of consolidation therapy in both arms of the trial for patients who achieve remission. We believe that multiple cycles of treatment in patients who respond may drive an even deeper response in patients treated with uproleselan. If this is the case, it could lengthen the duration of remission with potential for additional benefit on survival. Key secondary endpoints of the Phase 3 trial will include the incidence of severe mucositis and remission rate, which will be assessed in a hierarchical fashion which may provide supportive data. We expect to have top-line results from this trial by the end of 2020.

Uproleselan received orphan drug designation from the FDA in May 2015 for the treatment of patients with AML. In June 2016, uproleselan received fast track designation from the FDA for the treatment of adult patients with relapsed or refractory AML and elderly patients aged 60 years or older with AML. In May 2017, uproleselan received Breakthrough Therapy designation from the FDA for the treatment of adult patients with relapsed or refractory AML. In May 2017, the European Commission, based on a favorable recommendation from the EMA Committee for Orphan Medicinal Products, granted orphan designation for uproleselan for the treatment of patients with AML. We recently received a response from the EMA to our request for scientific advice with respect to our Marketing Authorization Application, or MAA development plan. Based on this guidance, we intend to conduct a Phase 3 clinical trial in Europe and pursue regulatory approval of uproleselan for treatment of AML.

In May 2018, we signed a Cooperative Research and Development Agreement, or CRADA, with the National Cancer Institute, or NCI, part of the National Institutes of Health. Under the terms of the CRADA, we will collaborate with both the NCI and the Alliance for Clinical Trials in Oncology to conduct a Phase 2/3 randomized, controlled clinical trial testing the addition of uproleselan to a standard cytarabine/daunorubicin chemotherapy regimen (7&3) in older adults with previously untreated AML who are suitable for intensive chemotherapy. The primary endpoint will be overall survival, which is defined as the time from the date of randomization to death from any cause, with a planned interim analysis based on event-free survival after the first 250 patients have been enrolled in the trial. The full trial is expected to enroll approximately 670 patients. Under the terms of the CRADA, the NCI may also fund additional research, including clinical trials involving pediatric patients with AML as well as preclinical experiments and clinical trials evaluating alternative chemotherapy regimens. We will supply uproleselan as well as provide financial support to augment data analysis and monitoring for the Phase 3 program. The trial opened for enrollment in early 2019 and enrolled the first patient in April 2019.

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In February 2018, we entered into an agreement with the Haemato Oncology Foundation for Adults in the Netherlands, or HOVON, to initiate and conduct a Phase 2 clinical trial to evaluate uproleselan in adults with newly diagnosed AML but who cannot tolerate intensive chemotherapy, as well as in patients with myelodysplastic syndrome, or MDS, and a high risk of leukemia. The HOVON trial will be the first to evaluate uproleselan, together with decitabine, in this underserved population of AML and MDS patients; these two populations represent a significant potential indication expansion opportunity for uproleselan. HOVON intends to enroll approximately 140 patients in the clinical trial, including a control arm. Patients will be evaluated after three cycles of therapy, and key efficacy endpoints will include remission rate, disease-free survival and overall survival. The trial is anticipated to be conducted in five countries across Europe.

We are also developing an additional drug candidate, GMI-1359, that simultaneously targets both E-selectin and a chemokine receptor known as CXCR4. Since E-selectin and CXCR4 are implicated in the retention of cancer cells in the bone marrow, we believe that targeting both E-selectin and CXCR4 with a single compound could improve efficacy in the treatment of solid tumors that often metastasize to bone, such as breast and prostate cancer, as compared to targeting CXCR4 alone. We recently completed a Phase 1 single-dose escalation trial of GMI-1359 in healthy volunteers. In this trial, volunteer participants received a single injection of GMI-1359, after which they were evaluated for safety, tolerability and PK. This randomized, double-blind, placebo-controlled, dose-escalation trial was conducted at a single site in the United States. GMI-1359 was generally well tolerated in this trial, with no subjects experiencing serious adverse events. We anticipate initiating a Phase 1b trial of GMI-1359 in breast cancer patients whose tumors have spread to bone in the second half of 2019. The trial will be conducted at Duke University and will evaluate dose escalation as well as safety and pharmacodynamic markers in these patients.

In addition to our programs described above, we are also advancing other preclinical-stage programs. These programs include small-molecule glycomimetic compounds that inhibit the protein galectin-3, which we believe may have potential to be used for the treatment of fibrosis, cancer and cardiovascular disease.

We commenced operations in 2003, and our operations to date have been limited to organizing and staffing our company, business planning, raising capital, developing our glycomimetics platform, identifying potential drug candidates, undertaking preclinical studies and conducting, both alone and in collaboration with third parties, clinical trials of rivipansel, uproleselan and GMI-1359. To date, we have financed our operations primarily through private placements of our securities, up-front and milestone payments under our collaboration with Pfizer, the net proceeds from our IPO in January 2014 and additional public offerings of common stock in 2016, 2017 and 2018, as well as proceeds from sales of common stock under at-the-market sales facilities with Cowen and Company LLC, or Cowen. We have no approved drugs currently available for sale, and substantially all of our revenue to date has been revenue from the up-front and milestone payments from Pfizer, although we have received nominal amounts of revenue under research grants.

Prior to our IPO, we raised an aggregate of $86.6 million to fund our operations, of which $22.5 million was an up-front payment under our collaboration with Pfizer and $64.1 million was from the sale of our convertible promissory notes and convertible preferred stock. The IPO provided us with net proceeds of $57.2 million, and we received a non-refundable milestone payment from Pfizer in May 2014 of $15.0 million. In August 2015, we received another non-refundable milestone payment from Pfizer of $20.0 million following the dosing of the first patient in the Phase 3 clinical trial of rivipansel. We received an additional $19.7 million in net proceeds from our public offering in June 2016, $86.8 million in net proceeds from our public offering in May 2017 and $128.4 million in net proceeds from our public offering in March 2018. During the years ended December 31, 2016 and 2017, we received an aggregate of $30.5 million of net proceeds from sales of our common stock pursuant to our at-the-market sales agreements with Cowen. There were no securities sold during the year ended December 31, 2018 or the three months

ended March 31, 2019 under our at-the-market sales agreement with Cowen.

Since inception, we have incurred significant operating losses. We have generated cumulative revenue of $58.6 million since our inception through March 31, 2019 primarily consisting of the $22.5 million up-front payment from Pfizer in 2011, the $15.0 million non-refundable milestone payment in May 2014 and the $20.0 million non-refundable milestone payment in August 2015. We had an accumulated deficit of $214.6 million as of March 31, 2019, and we expect to continue to incur significant expenses and operating losses over at least the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year, depending on the timing of our clinical trials, the

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receipt of milestone payments, if any, under our collaboration with Pfizer, and our expenditures on other research and development activities. We anticipate that our expenses will increase substantially as we:

- initiate and conduct our planned clinical trials of uproleselan and GMI-1359, including fulfilling our funding and supply commitments related to clinical trials of uproleselan being conducted by or in collaboration with third parties;
- manufacture additional uproleselan drug supplies for validation, new drug application and commercial batches;
- continue the research and development of our pre-clinical drug candidates;
- seek to discover and develop additional drug candidates;
- seek regulatory approvals for any drug candidates other than rivipansel that successfully complete clinical trials;
- ultimately establish a sales, marketing and distribution infrastructure and scale up external manufacturing capabilities to commercialize any drug candidates other than rivipansel for which we may obtain regulatory approval;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, quality control and scientific personnel; and
- add operational, financial and management information systems and personnel, including personnel to support our drug development and potential future commercialization efforts.

To fund further operations, we will need to raise capital. We may obtain additional financing in the future through the issuance of our common stock, through other equity or debt financings or through collaborations or partnerships with other companies. We may not be able to raise additional capital on terms acceptable to us, or at all, and any failure to raise capital as and when needed could compromise our ability to execute on our business plan. Although it is difficult to predict future liquidity requirements, we believe that our existing cash and cash equivalents, together with interest thereon, will be sufficient to fund our operations at least through our receipt of preliminary results from our Phase 3 clinical trial of uproleselan in individuals with relapsed/refractory AML, which we currently expect to occur by the end of 2020. However, our ability to successfully transition to profitability will be dependent upon achieving a level of revenues adequate to support our cost structure. We cannot assure you that we will ever be profitable or generate positive cash flow from operating activities.

Our Collaboration with Pfizer

In October 2011, we entered into the license agreement with Pfizer under which we granted Pfizer an exclusive worldwide license to develop and commercialize products containing rivipansel for all fields and uses. The license also covers specified back-up compounds along with modifications of and improvements to rivipansel that meet defined chemical properties. Pfizer is required to use commercially reasonable efforts, at its expense, to develop, obtain regulatory approval for and commercialize rivipansel for sickle cell disease in the United States. Under the terms of the agreement, we received a $22.5 million up-front payment. We are also eligible to earn potential milestone payments of up to $115.0 million upon the achievement of specified development milestones, including the dosing of the first patients in Phase 3 clinical trials for up to two indications and the first commercial sale of a licensed product in the United States and selected European countries for up to two indications, up to $70.0 million upon the achievement of specified regulatory milestones, including the acceptance of our filings for regulatory approval by regulatory authorities in the United States and Europe for up to two indications, and up to $135.0 million upon the achievement of specified levels of annual net sales of licensed products. We are also eligible to receive tiered royalties for each licensed product, with percentages ranging from the low double digits to the low teens, based on net sales worldwide, subject to reductions in specified circumstances.

The first potential milestone payment under the Pfizer agreement was $35.0 million upon the initiation of dosing of the first patient in a Phase 3 clinical trial of rivipansel by Pfizer. Based on certain terms of the agreement, Pfizer made

a $15.0 million non-refundable partial milestone payment to us in May 2014, which we recognized as revenue in May

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2014, when earned, and the dosing of the first patient in the Phase 3 clinical trial in June 2015 triggered the remaining $20.0 million milestone payment to us. We recorded the $20.0 million milestone payment as revenue in June 2015. There were no milestone payments received or recorded as revenue from Pfizer for the three months ended March 31, 2019 or 2018.

We entered into a research services agreement with the University of Basel, or the University, for biological evaluation of selectin antagonists. While the scope of work under the research agreement with the University ended in 2017, certain patents covering the rivipansel compound are subject to provisions of the Research Agreement. Under the terms of the Research Agreement, we owe the University 10% of all milestone and royalty payments received from Pfizer with respect to rivipansel. There were no payments due to the University for the three months ended March 31, 2019 or 2018.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to our revenue recognition, accrued research and development expenses, stock-based compensation expense and income taxes. We base our estimates on historical experience, known trends and events and various other factors that we believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other resources. Actual results may differ from these estimates and judgments under different assumptions or conditions. We periodically review our estimates in light of changes in circumstances, facts and experience. The effects of material revisions in estimates are reflected in our financial statements prospectively from the date of the change in estimate.

We define our critical accounting policies as those accounting principles generally accepted in the United States that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. For a description of our critical accounting policies, please see the disclosures in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2018. There have not been any material changes to our critical accounting policies since December 31, 2018.

Components of Operating Results

Revenue

To date, we have not generated any revenue from the sale of our drug candidates and do not expect to generate any revenue from the sale of drugs in the near future. Substantially all of our revenue recognized to date has consisted of the up-front and milestone payments under our agreement with Pfizer.

Since our inception, we have also recognized a nominal amount of revenue under research grant contracts, generally to the extent of our costs incurred in connection with specific research or development activities.

Research and Development

Research and development expenses consist of expenses incurred in performing research and development activities, including compensation and benefits for full-time research and development employees, facilities expenses, overhead expenses, cost of laboratory supplies, clinical trial and related clinical manufacturing expenses, fees paid to contract research organizations and other consultants and other outside expenses. Other preclinical research and platform programs include activities related to exploratory efforts, target validation, lead optimization for our preclinical programs and our proprietary glycomimetics platform.

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To date, our research and development expenses have related primarily to the development of rivipansel, uproleselan and our other drug candidates. In April 2013, when we completed our Phase 2 clinical trial of rivipansel, all further clinical development obligations associated with rivipansel shifted to Pfizer.

We do not currently utilize a formal time allocation system to capture expenses on a project-by-project basis because we are organized and record expense by functional department and our employees may allocate time to more than one development project. Accordingly, we only allocate a portion of our research and development expenses by functional area and by drug candidate.

Research and development costs are expensed as incurred. Non-refundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or the services are performed.

Research and development activities are central to our business model. Drug candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later stage clinical trials. We expect our research and development expenses to increase over the next several years as we seek to progress uproleselan, GMI-1359 and our other drug candidates through clinical development. For example, as we prepare to potentially submit an application for marketing approval for uproleselan, we will incur substantial expenses in scaling up the production and manufacturing of uproleselan. However, it is difficult to determine with certainty the duration and completion costs of our current or future preclinical studies and clinical trials of our drug candidates, or if, when or to what extent we will generate revenues from the commercialization and sale of any of our drug candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our drug candidates.

The duration, costs and timing of clinical trials and development of our drug candidates will depend on a variety of factors that include:

- per patient trial costs;
- the number of patients that participate in the trials;
- the number of sites included in the trials;
- the countries in which the trial is conducted;

- the length of time required to enroll eligible patients;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up; and
- the safety and efficacy profile of the drug candidate.

In addition, the probability of success for each drug candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability. We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each drug candidate, as well as an assessment of each drug candidate's commercial potential.

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General and Administrative

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in executive, finance, accounting, business development and human resources functions. Other significant costs include facility costs not otherwise included in research and development expenses, legal fees relating to patent and corporate matters and fees for accounting and consulting services. We anticipate that our general and administrative expenses will increase in the future to support our continued research and development activities.

Interest Income

Interest income consists of interest earned on our cash and cash equivalents.

Results of Operations for the Three Months Ended March 31, 2019 and 2018

The following table sets forth our results of operations for the three months ended March 31, 2019 and 2018:

| | Three Months Ended March 31, | | Period-to-Period |
|---|---|---|---|
| (in thousands) | 2019 | 2018 | Change |
| Revenue | $ — | $ — | $ — |
| Costs and expenses: | | | |
| Research and development expense | 11,773 | 9,022 | 2,751 |
| General and administrative expense | 3,360 | 2,855 | 505 |
| Total costs and expenses | 15,133 | 11,877 | 3,256 |
| Loss from operations | (15,133) | (11,877) | (3,256) |
| Interest income | 1,049 | 364 | 685 |
| Net loss and comprehensive loss | $ (14,084) | $ (11,513) | $ (2,571) |

Research and Development Expense

The following table summarizes our research and development expense by functional area for the three months ended March 31, 2019 and 2018:

| (in thousands) | Three Months Ended March 31, 2019 | 2018 | Period-to-Period Change |
|---|---|---|---|
| Clinical development | $ 2,607 | $ 858 | $ 1,749 |
| Manufacturing and formulation | 5,244 | 4,889 | 355 |
| Contract research services, consulting and other costs | 594 | 501 | 93 |
| Laboratory costs | 502 | 490 | 12 |
| Personnel-related | 2,318 | 1,859 | 459 |
| Stock-based compensation | 508 | 425 | 83 |
| Research and development expense | $ 11,773 | $ 9,022 | $ 2,751 |

During the three months ended March 31, 2019, our research and development expense increased by $2.8 million, or 30%, compared to the same period in 2018. This increase was primarily the result of the higher clinical expenses related to the start-up and enrollment of patients in the Phase 3 clinical trial of uproleselan in the quarter ended March 31, 2019 compared to the quarter ended March 31, 2018. Personnel-related and stock-based compensation expenses increased due an increase in our research and development headcount compared to the same period in 2018, as well as annual salary adjustments and stock option awards granted in the first quarter of 2019.

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The following table summarizes our research and development expense by drug candidate for the three months ended March 31, 2019 and 2018:

| (in thousands) | Three Months Ended March 31, 2019 | 2018 | Period-to-Period Change |
|---|---|---|---|
| Uproleselan | $ 7,874 | $ 6,024 | $ 1,850 |
| GMI-1359 | 166 | 5 | 161 |
| Other research and development | 907 | 709 | 198 |
| Personnel-related and stock-based compensation | 2,826 | 2,284 | 542 |
| Research and development expense | $ 11,773 | $ 9,022 | $ 2,751 |

General and Administrative Expense

The following table summarizes the components of our general and administrative expense for the three months ended March 31, 2019 and 2018:

| (in thousands) | Three Months Ended March 31, 2019 | 2018 | Period-to-Period Change |
|---|---|---|---|
| Personnel-related | $ 1,134 | $ 955 | $ 179 |
| Stock-based compensation | 875 | 691 | 184 |
| Legal, consulting and other professional expenses | 1,135 | 1,029 | 106 |
| Other | 216 | 180 | 36 |
| General and administrative expense | $ 3,360 | $ 2,855 | $ 505 |

During the three months ended March 31, 2019, our general and administrative expense increased by $505,000, or 18%, compared to the same period in 2018. Personnel-related and stock-based compensation expenses increased due an increase in general and administrative headcount compared to the same period in 2018, as well as annual salary adjustments and stock option awards granted in the first quarter of 2019.

Interest Income

Interest income increased by $685,000 to $1.0 million for the three months ended March 31, 2019 from $364,000 for the three months ended March 31, 2018 due to higher average cash balances following our public offering of common stock in March 2018.

Liquidity and Capital Resources

Sources of Liquidity

We have financed our operations primarily through public offerings and private placements of our capital stock, as well as up-front and milestone payments from Pfizer. As of March 31, 2019, we had $195.6 million in cash and cash equivalents.

We are potentially eligible to earn a significant amount of milestone payments and royalties under our agreement with Pfizer. Our ability to earn these payments and their timing is dependent upon the outcome of Pfizer's activities including the results of the ongoing Phase 3 clinical trial and is uncertain at this time.

In September 2017, we entered into an at-the-market sales agreement under which we may offer and sell, from time to time at our sole discretion, shares of our common stock having an aggregate offering price of up to $100.0 million through Cowen as our sales agent. As of the date of this report, we have sold an aggregate of 1,600,000 shares of our common stock under this agreement for net proceeds of $19.3 million. There were no sales under the at-the-market sales agreement for the three months ended March 31, 2019 or 2018.

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Funding Requirements

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, third-party clinical research and development services, laboratory and related supplies, clinical and manufacturing costs, legal and other regulatory expenses and general overhead costs.

The successful development of any of our drug candidates is highly uncertain. As such, at this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of uproleselan or our other drug candidates. We are also unable to predict when, if ever, material net cash inflows will commence from rivipansel or uproleselan. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- successful enrollment in, and completion of, clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for drug candidates;
- launching commercial sales of drugs, if and when approved, whether alone or in collaboration with others; and
- obtaining and maintaining healthcare coverage and adequate reimbursement.

A change in the outcome of any of these variables with respect to the development of any of our drug candidates would significantly change the costs and timing associated with the development of that drug candidate. Because our drug candidates are in various stages of clinical and preclinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our drug candidates or whether, or when, we may achieve profitability. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity or debt financings and collaboration arrangements, including our existing collaboration with Pfizer. Except for Pfizer’s obligation to make potential future milestone and royalty payments under our agreement with them, we do not have any committed external source of liquidity.

To the extent that we raise additional capital through the future sale of equity or debt, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders. If we raise additional funds through the issuance of convertible debt securities, these securities could contain covenants that would restrict our operations.

We may require additional capital beyond our currently anticipated amounts. Additional capital may not be available on reasonable terms, or at all. If we raise additional funds through collaboration arrangements in the future, we may have to relinquish valuable rights to our drug candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts or grant rights to develop and market drug candidates that we would otherwise prefer to develop and market ourselves.

Outlook

Based on our research and development plans and our timing expectations related to the progress of our programs, we expect that our existing cash and cash equivalents will enable us to fund our operations at least through our receipt of preliminary results from our Phase 3 clinical trial of uproleselan in individuals with relapsed/refractory AML, which we currently expect to occur by the end of 2020. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we expect. Additionally, the process of testing drug candidates in clinical trials is costly, and the timing of progress in these trials is uncertain.

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Cash Flows

The following is a summary of our cash flows for the three months ended March 31, 2019 and 2018:

| | Three Months Ended March 31, | |
|---|---|---|
| (in thousands) | 2019 | 2018 |
| Net cash provided by (used in): | | |
| Operating activities | $ (14,348) | $ (10,209) |
| Investing activities | (40) | (17) |
| Financing activities | 31 | 128,933 |
| Net change in cash and cash equivalents | $ (14,357) | $ 118,707 |

Operating Activities

Net cash used in operating activities for the three months ended March 31, 2019 and 2018 was primarily the result of ongoing costs associated with our uproleselan clinical development programs, which for 2019 also included significant manufacturing costs and costs associated with the enrollment of patients in our Phase 3 clinical trial.

Investing Activities

Net cash used in investing activities for the three months ended March 31, 2019 and 2018 was for computer and laboratory equipment.

Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2019 consisted of proceeds from stock option exercises. Net cash provided by financing activities during the three months ended March 31, 2018 consisted of the net proceeds of $128.6 million from our public offering in March 2018 and $300,000 in proceeds from stock option and warrant exercises.

Off-Balance Sheet Arrangements

During the three months ended March 31, 2019, we did not have, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

JOBS Act

In April 2012, the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, was enacted. Section 107(b) of the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period, and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates. As of March 31, 2019 and December 31, 2018, we had cash and cash equivalents of $195.6 million and $209.9 million, respectively. We generally hold our cash in interest-bearing money market accounts. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term maturities of our cash equivalents and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents.

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Item 4. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures

The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Security and Exchange Commission’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that such information is accumulated and communicated to a company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a control system, misstatements due to error or fraud may occur and not be detected.

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2019, the end of the period covered by this Quarterly Report on Form 10-Q. Based upon such evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of such date at the reasonable assurance level.

(b) Changes in Internal Controls Over Financial Reporting

There have not been any changes in our internal controls over financial reporting during our fiscal quarter ended March 31, 2019 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we are subject to litigation and claims arising in the ordinary course of business. We are not currently a party to any material legal proceedings and we are not aware of any pending or threatened legal proceeding against us that we believe could have a material adverse effect on our business, operating results, cash flows or financial condition.

Item 1A. Risk Factors

Our business is subject to risks and events that, if they occur, could adversely affect our financial condition and results of operations and the trading price of our securities. Our risk factors as of the date of this quarterly report on Form 10 Q have not changed materially from those described in “Part I, Item 1A. Risk Factors” of our Annual Report on Form 10 K for the fiscal year ended December 31, 2018, filed with the Securities and Exchange Commission on March 6, 2019.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

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Item 6. Exhibits

| Exhibit No. | Document |
|---|---|
| 3.1 | Amended and Restated Certificate of Incorporation of the Registrant (incorporated herein by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8_K (File No. 001_36177), filed with the Commission on January 15, 2014). |
| 3.2 | Amended and Restated Bylaws of the Registrant (incorporated herein by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8_K (File No. 001_36177), filed with the Commission on January 15, 2014). |
| 4.1 | Specimen stock certificate evidencing shares of Common Stock (incorporated herein by reference to Exhibit 4.2 to Amendment No. 2 to the Registrant's Registration Statement on Form S_1 (File No. 333_191567), filed with the Commission on October 31, 2013). |
| 10.1* | Amended and Restated Executive Employment Agreement, effective as of March 1, 2019, by and between the Registrant and Armand Girard. |
| 31.1* | Certification of Principal Executive Officer under Section 302 of the Sarbanes-Oxley Act. |
| 31.2* | Certification of Principal Financial Officer under Section 302 of the Sarbanes-Oxley Act. |
| 32.1** | Certifications of Principal Executive Officer and Principal Financial Officer under Section 906 of the Sarbanes-Oxley Act. |
| 101.INS | XBRL Instance Document |
| 101.SCH | XBRL Taxonomy Extension Schema Document |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase Document |
| 101.LAB | XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document |

* Filed herewith

** These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof,

regardless of any general incorporation language in such filing.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

GLYCOMIMETICS, INC.

Date: May 2, 2019 By: /s/ Brian M. Hahn
Brian M. Hahn
Chief Financial Officer
(On behalf of the Registrant and as Principal Financial Officer)