
TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION

Page

| | | |
|-------------------------|--|----|
| Item 1. | Financial Statements | |
| | Condensed Consolidated Balance Sheets as of June 30, 2019 and 2018 | 19 |





[Table of Contents](#)

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PART I. FINANCIAL INFORMATION

Unless the context otherwise requires, all references in this Quarterly Report on Form 10-Q to the “Company”, “OPKO”, “we”, “our”, “ours”, and “us” refer to OPKO Health, Inc., a Delaware corporation, including our wholly-owned subsidiaries.

Item 1. Financial Statements

The accompanying unaudited Notes to Condensed Consolidated Financial Statements are an integral part of these statements.

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[Redacted content]

Condensed Consolidated Balance Sheet and are amortized over the shorter of their useful lives or the expected term of their related leases.

Impairment of long-lived assets. Long-lived assets, such as property and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, then an impairment charge is recognized for the amount by which the carrying amount of the asset exceeds the fair value of the asset.

Income taxes. Income taxes are accounted for under the asset-and-liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and the respective tax bases and for operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. We periodically evaluate the realizability of our net deferred tax assets. Our tax accruals are analyzed periodically and adjustments are made as events occur to warrant such adjustment. Valuation allowances on certain U.S. deferred tax assets and non-U.S. deferred tax assets are established, because realization of these tax benefits through future taxable income does not meet the more-likely-than-not threshold.

We operate in various countries and tax jurisdictions globally. For interim reporting purposes, we record income taxes based on the expected effective income tax rate, taking into consideration year to date and global forecasted tax results. For the three and six months ended June 30, 2019, the tax rate differed from the U.S. federal statutory rate of 21% primarily due to the valuation allowance against certain U.S. and non-U.S. deferred tax assets, the relative mix in earnings and losses in the U.S. versus foreign tax jurisdictions, and the impact of certain discrete tax events and operating results in tax jurisdictions which do not result in a tax benefit.

Revenue recognition. We recognize revenue when a customer obtains control of promised goods or services in accordance with Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers* (“Topic 606”). The amount of revenue that is recorded reflects the consideration that we expect to receive in exchange for those goods or services. We apply the following five-step model in order to determine this amount: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations.

2016-02, "Leases (Topic 842)," which requires organizations that lease assets with lease terms of more than 12 months to recognize assets and liabilities for the rights and obligations created by those leases on their balance sheets. ASU 2016-02, as amended and codified under Topic 842, requires new qualitative and quantitative disclosures to help investors and other financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. As required, we adopted Topic 842 on January 1, 2019 using the modified retrospective approach for all lease arrangements at the beginning or the period of adoption. Results for reporting periods beginning January 1, 2019 are presented under Topic 842, while prior period amounts were not adjusted and continue to be reported in accordance our historic accounting under ASC 840.

For leases that commenced before the effective date of Topic 842, we elected the permitted practical expedients to not reassess the following: (i) whether any expired or existing contracts contain leases (ii) the lease classification for any expired or existing leases and (iii) initial direct costs for any existing leases. We also elected the policy of not recording leases on our Condensed Consolidated Balance Sheet when the leases have a term of 12 months or less and we elected not to separate nonlease components from lease components and instead account for each separate lease component and the nonlease components associated with that lease component as a single lease component.

The adoption of Topic 842 resulted in the recognition of operating lease liabilities of approximately \$33.7 million and operating lease right-to-use assets of approximately \$33.3 million as of March 31, 2019, primarily related to operating leases for our diagnostic facilities, based on the present value of lease payments over the lease term. There was no cumulative-effect adjustment to beginning Accumulated deficit on the Condensed Consolidated Balance Sheet. The accounting for our finance leases remains substantially unchanged, as finance lease liabilities and their corresponding right-to-use assets were already recorded on the Condensed Consolidated Balance Sheet under the previous guidance. The adoption of Topic 842 did not have a significant effect on our results of operations or cash flows. Refer to Note 15 for additional disclosures required by Topic 842.

In February 2018, the FASB issued ASU No. 2018-02, "Income Statement-Reporting Comprehensive Income (Topic 220)." This standard provides an option to reclassify stranded tax effects within accumulated other comprehensive loss to retained earnings due to the U.S. federal corporate income tax rate change in the Tax Cuts and Jobs Act of 2017. This standard is effective for interim and annual reporting periods beginning after December 15, 2018. We adopted this standard effective January 1, 2019 with the election not to reclassify immaterial amounts of stranded tax effects from accumulated other comprehensive loss to retained earnings.

In June 2018, the FASB issued ASU No. 2018-07, "Compensation - Stock Compensation (Topic 718)," which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees. The adoption of ASU 2018-07 on January 1, 2019, did not have a significant impact on our Condensed Consolidated Financial Statements.

Pending accounting pronouncements.

In June 2016, the FASB issued ASU No. 2016-13, "Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments," which amends the impairment model by requiring entities to use a forward-looking approach based on expected losses rather than incurred losses to estimate credit losses on certain types of financial instruments, including trade receivables. This may result in the earlier recognition of allowances for losses. The ASU is effective for public entities for fiscal years beginning after December 15, 2019, with early adoption permitted. We are currently evaluating the impact of this new guidance on our Condensed Consolidated Financial Statements.

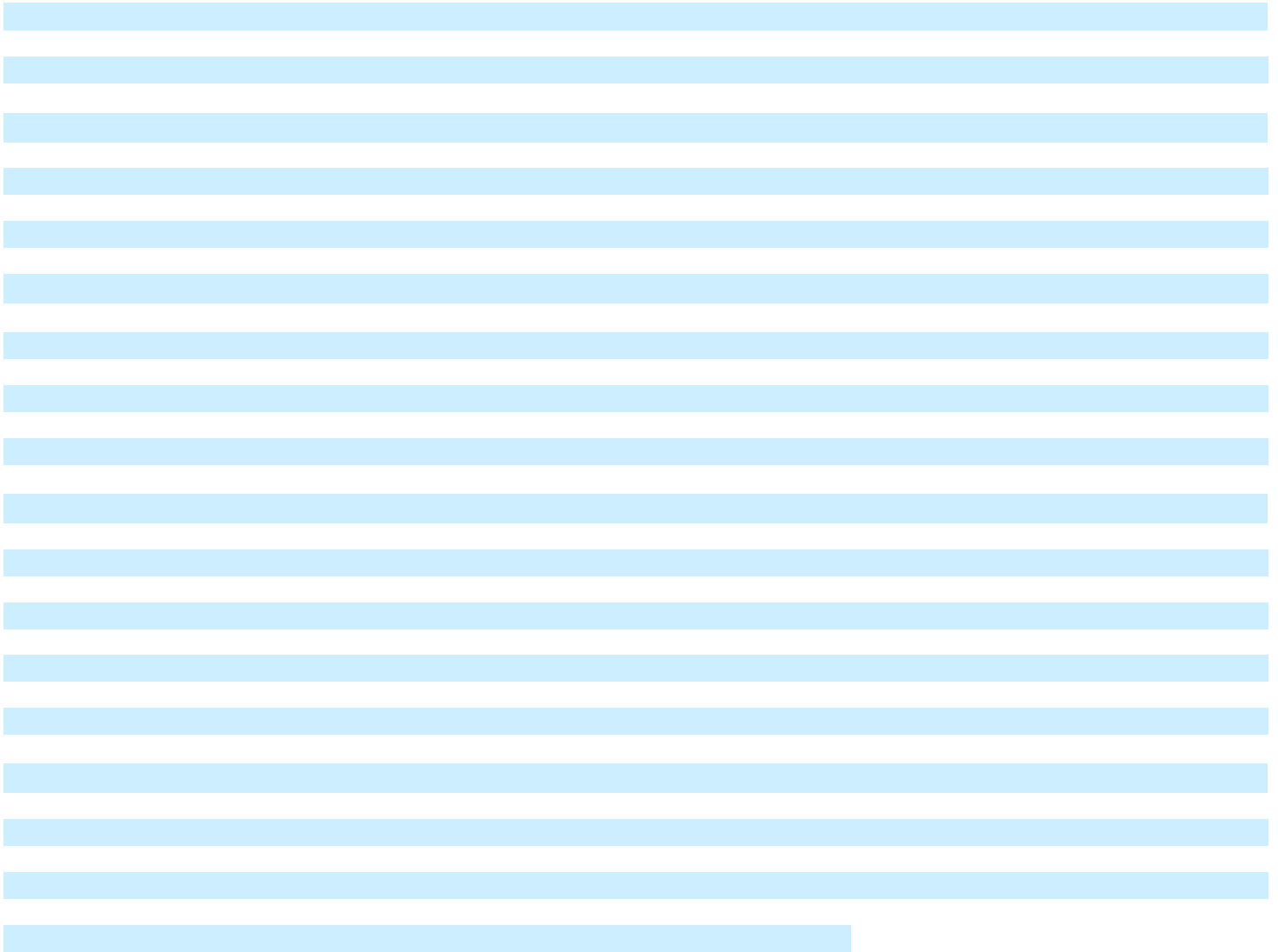


Table of Contents

For accounting and financial reporting purposes, we combined these embedded derivatives and valued them together as one unit of accounting. In 2017, certain terms of the embedded derivatives expired pursuant to the original agreement and the embedded derivatives no longer met the criteria to be separated from the host contract and, as a result, the embedded derivatives were no longer required to be valued separate and apart from the 2033 Senior Notes and were reclassified to additional paid in capital.

From 2013 to 2016, holders of the 2033 Senior Notes converted \$143.2 million in aggregate principal amount into an aggregate of 21,539,873 shares of the Company's Common Stock.

In November 2015, BioReference and certain of its subsidiaries entered into a credit agreement with JPMorgan Chase Bank, N.A. ("CB"), as lender and administrative agent, as amended (the "Credit Agreement"). The Credit Agreement provides for a \$100.0 million secured revolving credit facility and includes a \$20.0 million sub-facility for swingline loans and a \$20.0 million sub-facility for the issuance of letters of credit. BioReference may increase the credit facility to up to \$275.0 million on a secured basis, subject to the satisfaction of specified conditions. The Credit Agreement matures on November 5, 2020 and is guaranteed by all of BioReference's domestic subsidiaries. The Credit Agreement is also secured by substantially all assets of BioReference and its domestic subsidiaries, as well as a non-recourse pledge by us of our equity interest in BioReference. Availability under the Credit Agreement is based on a borrowing base composed of eligible accounts receivables of BioReference and certain of its subsidiaries, as specified therein. As of September 30, 2017, \$1.7 million additional funds were available to be borrowed under the Credit Agreement. Principal under the Credit Agreement is due upon maturity on November 5, 2020.

At BioReference's option, borrowings under the Credit Agreement or Credit Agreement may be used for



| | June 30, 2019 |
|-----------------------------------|-----------------------------|
| | Contingent consideration |
| <u>(In thousands)</u> | |
| Balance at December 31, 2018 | \$ 24,537 |
| Change in fair value: | |
| Included in results of operations | 1,031 |
| Balance at June 30, 2019 | \$ 25,568 |

The estimated fair values of our financial instruments have been determined by using available market information and what we believe to be appropriate valuation methodologies. We use the following methods and assumptions in estimating fair value:

Contingent consideration – We estimate the fair value of the contingent consideration utilizing a discounted cash flow model for the expected payments based on estimated timing and expected revenues. We use several discount rates depending on each type of contingent consideration related to OPKO Diagnostics, CURNA and OPKO Renal transactions. If estimated future sales were to decrease by 10%, the contingent consideration related to OPKO Renal, which represents the majority of our contingent consideration liability, would decrease by \$1.4 million. As of June 30, 2019, of the \$25.6 million of contingent consideration, \$5.4 million is recorded in Accrued expenses and \$20.2 million is recorded in Other long-term liabilities. As of December 31, 2018, of the \$24.5 million of contingent consideration, \$2.4 million is recorded in Accrued expenses and \$22.2 million is recorded in Other long-term liabilities.

The Company owns approximately 9% of Pharmsynthez and Pharmsynthez is Xenetic's largest and controlling stockholder. Dr. Richard Lerner, a director of the Company, is a co-inventor of the technology and received 31,240 shares of Xenetic upon the closing of the Xenetic transactions. Adam Logal, our Senior Vice President and Chief Financial Officer, is a director of Xenetic.

On November 8, 2018, we entered into stock purchase agreements with certain investors pursuant to which we agreed to sell to such investors in private placements an aggregate of approximately 26.5 million shares of our Common Stock at a purchase price of \$3.49 per share, which was the closing bid price of our Common Stock on the NASDAQ on such date, for an aggregate purchase price of \$92.5 million. The investors in the private placements included an affiliate of Dr. Frost (\$70 million), and Dr. Hsiao (\$2 million).

On November 8, 2018, we entered into a credit agreement with an affiliate of Dr. Frost, pursuant to which the lender committed to provide us with an unsecured line of credit in the amount of \$60 million. Borrowings under the line of credit bore interest at a rate of 10% per annum and could have been repaid and reborrowed at any time. The credit agreement included various customary remedies for the lender following an event of default, including the acceleration of repayment of outstanding amounts under line of credit. The line of credit would have matured on November 8, 2023. We repaid approximately \$28.8 million that was borrowed in 2019 and terminated the line of credit on or around February 20, 2019.

In February 2018, we issued the 2023 Convertible Notes in the aggregate principal amount of \$55.0 million. Refer to Note 6. Purchasers of the 2023 Convertible Notes included Dr. Hsiao and an affiliate of Dr. Frost.

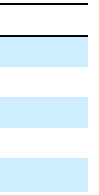
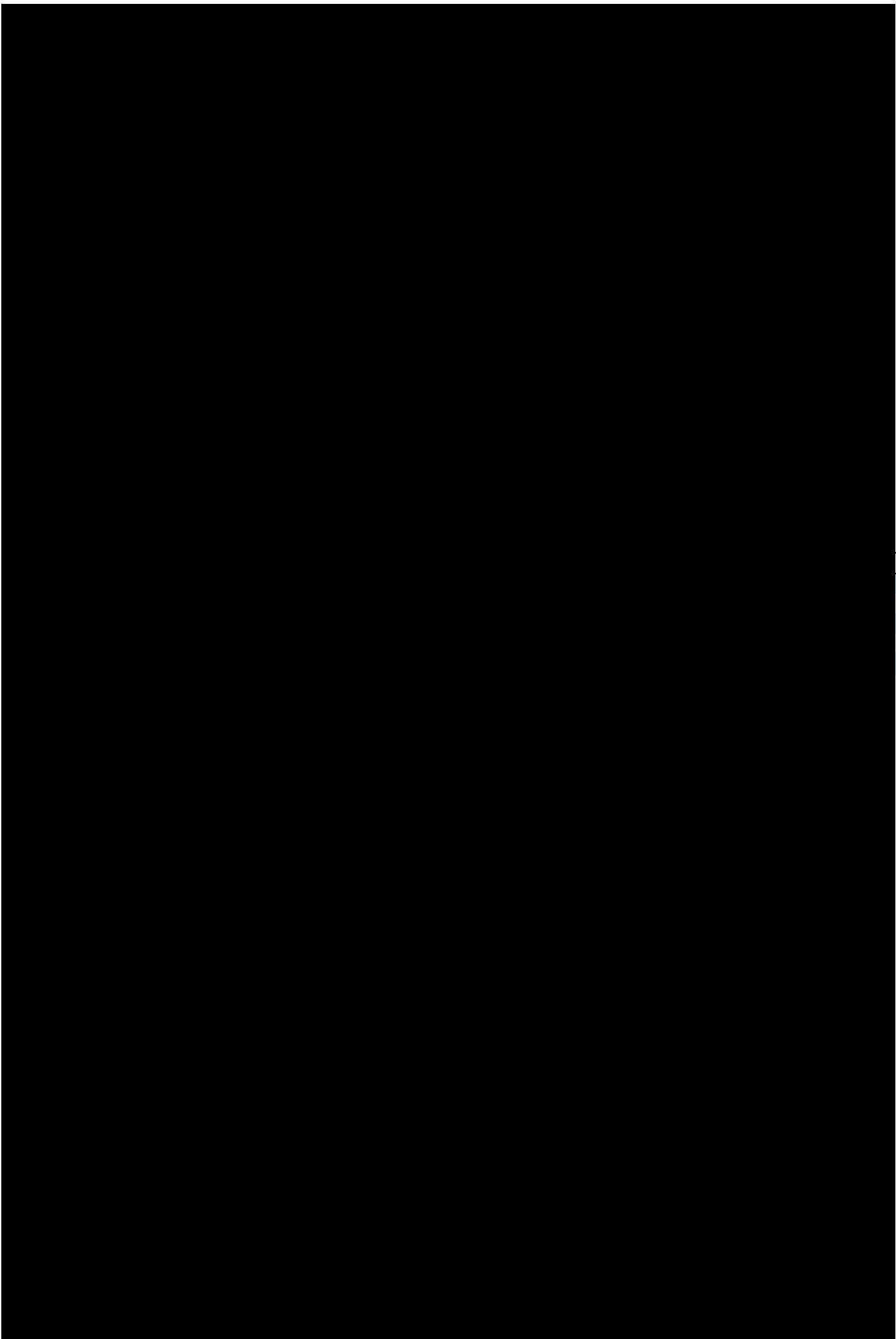
We hold investments in Zebra (ownership 29%), Neovasc (5%), ChromaDex Corporation (0.1%), MabVax (1%), COCP (8%), NIMS (1%), Eloxx (4%), and BioCardia (5%). These investments were considered related party transactions as a result of our executive management's ownership interests and/or board representation in these entities. See further discussion of our investments in Note 5.

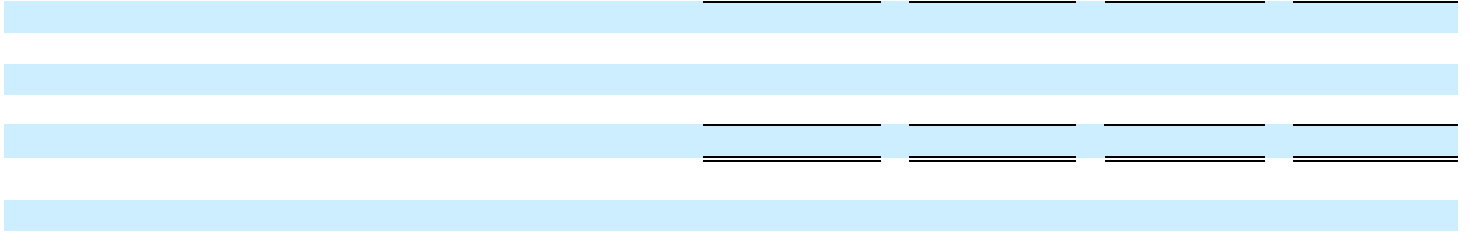
In February 2018, we invested an additional \$1.0 million in COCP for a convertible note, which was converted into 538,544 shares of its common stock in May 2018. In April 2017, we invested an additional \$1.0 million in COCP for 138,889 shares of its common stock.

In November 2017, we invested an additional \$3.0 million in Neovasc for 20,547 shares of its common stock, 20,547 Series A warrants, 20,547 Series B warrants and 8,221 Series C warrants, after adjusting for a 1-for-100 reverse stock split in 2018. In April 2018, we exercised the Series B warrants in a cashless exercise and received 1,069,090 shares of Neovasc common stock. In the first quarter of 2019, we exercised the Series C warrants for \$1.2 million and exchanged the Series A warrants and received an additional 2,663,326 shares of Neovasc common stock.

In November 2016, we entered into a Pledge Agreement with the Museum of Science, Inc. and the Museum of Science Endowment Fund, Inc. pursuant to which we will contribute an aggregate of \$1.0 million over a four-year period for constructing, equipping and the general operation of the Frost Science Museum. Dr. Frost and Mr. Richard Pfenninger serve on the Board of Trustees of the Frost Science Museum and Mr. Pfenninger is the Vice Chairman of the Board of Trustees.

We lease office space from Frost Real Estate Holdings, LLC ("Frost Holdings") in Miami, Florida, where our principal executive offices are located. Effective January 1, 2019, we entered into an amendment to our lease.





combined performance oblig



the Sales Milestones as royalties and Sales Milestones payments will be recognized as revenue in the period in which the associated milestone is achieved or sales occur, assuming all other revenue recognition criteria are met.

Pfizer Inc.

In December 2014, we entered into an exclusive worldwide agreement (the “Pfizer Agreement”) with Pfizer Inc. (“Pfizer”) for the development and commercialization of our long-acting hGH-CTP for the treatment of growth hormone deficiency (“GHD”) in adults and children, as well as for the treatment of growth failure in children born small for gestational age (the “Pfizer Transaction”).

The Pfizer Transaction closed in January 2015. Under the terms of the Pfizer Transaction, we received non-refundable and non-creditable upfront payments of \$295.0 million and are eligible to receive up to an additional \$275.0 million upon the achievement of certain regulatory milestones. Pfizer received the exclusive license to commercialize hGH-CTP worldwide. In addition, we are eligible to receive initial tiered royalty payments associated with the commercialization of hGH-CTP for Adult GHD with percentage rates ranging from the high teens to mid-twenties. Upon the launch of hGH-CTP for Pediatric GHD in certain major markets, the royalties will transition to regional, tiered gross profit sharing for both hGH-CTP and Pfizer’s Genotropin®.

The agreement with Pfizer will terminate at the time of the last sale of the licensed product, unless earlier terminated as permitted under the Pfizer Agreement. In addition to termination rights for material breach and bankruptcy, Pfizer is permitted to terminate the Pfizer Agreement in its entirety, or with respect to one or more



any time during the term for any reason on three months' written notice. TESARO announced during the first quarter of 2018 that it has elected to suspend further distribution of Varubi IV.

TESARO assigned its rights and obligations under the agreement to TerSera Therapeutics LLC ("TerSera") in June 2018 pursuant to an asset purchase agreement. Under the asset purchase agreement, TerSera is responsible for VARUBI in the U.S. and Canada and TESARO can continue to commercialize VARUBY® in Europe and the rest of the world through a sublicense with TerSera.

Pharmsynthez

In April 2013, we entered into a series of concurrent transactions with Pharmsynthez, a Russian pharmaceutical company traded on the Moscow Stock Exchange, pursuant to which we acquired an equity method investment in Pharmsynthez (ownership percentage not yet determined).

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

OVERVIEW

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Interest expense. Interest expense for the three months ended June 30, 2019 and 2018 was \$5.5 million and \$2.7 million, respectively. Interest expense is principally related to interest incurred on the 2025 Notes, the 2023 Convertible Notes, the 2033 Senior Notes, and BioReference’s outstanding debt under its credit facility. The increase in interest expense for the three months ended June 30, 2019 was primarily due to interest incurred on the 2025 Notes and 2023 Convertible Notes.

Fair value changes of derivative instruments, net. Fair value changes of derivative instruments, net for the three months ended June 30, 2019 and 2018, was \$0.4 million of expense and \$2.2 million of income, respectively. Derivative income for the three months ended June 30, 2019 principally related to the change in fair value of warrants to purchase additional shares of Xenetic. Derivative income for the three months ended June 30, 2018 principally related to the change in the fair value of warrants to purchase additional shares of Neovasc, Inc. and Xenetic.

Other income (expense), net. Other income (expense), net for the three months ended June 30, 2019 and 2018, was \$5.9 million of expense and \$8.6 million of income, respectively. Other income (expense) for the three months ended June 30, 2019 and 2018 primarily consisted of net unrealized gains (losses) recognized during the period on equity securities.

Income tax provision. Our income tax provision for the three months ended June 30, 2019 and 2018 was \$1.1 million and \$2.0 million, respectively, and reflects quarterly results using our expected effective tax rate. For the three months ended June 30, 2019, the tax rate differed from the U.S. federal statutory rate of 21% primarily due to the relative mix in earnings and losses in the U.S. versus foreign tax jurisdictions and the impact of certain discrete tax events and operating results in tax jurisdictions which do not result in a tax benefit.

Loss from investments in investees. We have made investments in other early stage companies that we perceive to have valuable proprietary technology and significant potential to create value for us as a shareholder or member. We account for these investments under the equity method of accounting, resulting in the recording of our proportionate share of their losses until our share of their loss exceeds our investment. Until the investees’ technologies are commercialized, if ever, we anticipate they will report a net loss. Loss from investments in investees

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2033 Senior Notes, and BioReference's outstanding debt under its credit facility. The increase in interest expense for these six months ended June 30, 2019 is primarily due to interest incurred on the 2025 Notes and 2023 Convertible Notes.

Fair value changes of derivative instruments, net. Fair value changes of derivative instruments, net for the six months ended June 30, 2019 and 2018, was \$0.0 million and \$3.6 million of income, respectively. Derivative income for the six months ended June 30, 2018 principally related to the change in the fair value of warrants to purchase additional shares of Neovasc, Inc. and Xenetic.

Other income (expense), net. Other income (expense), net for the six months ended June 30, 2019 and 2018, was \$4.9 million of expense and \$10.5 million of income, respectively.

LIQUIDITY AND CAPITAL RESOURCES

At June 30, 2019, we had cash and cash equivalents of approximately \$111.1 million. Cash used in operations of \$102.6 million during 2019 principally reflects general and administrative expenses in connection with our corporate operations, research and development activities and commercialization activities related to *Rayaldee*. Cash used in investing activities in 2019 primarily reflects capital expenditures of \$6.4 million. Cash provided by financing activities primarily reflects the issuance of the 2025 Notes in February 2019 for net proceeds of \$192.5 million, which was partially offset by the redemption of \$28.8 million principal amount of 2033 Senior Notes and repayments on BioReference's line of credit with JPMorgan Chase Bank, N.A. ("CB"). We have not generated sustained positive cash flow sufficient to offset our operating and other expenses and our primary source of cash has been from the public and private placement of stock, the issuance of the 2033 Senior Notes, 2023 Convertible Notes and 2025 Notes and credit facilities available to us.

In February 2019, we issued \$200.0 million aggregate principal amount of



[Table of Contents](#)

Item 4. Controls and Procedures

Disclosure Controls an

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not Applicable.

Item 5. Other Information

None.

Item 6. Exhibits

| | |
|---|---|
| Exhibit 3.1⁽¹⁾ | Amended and Restated Certificate of Incorporation. |
| Exhibit 31.1 | Certification by Phillip Frost, Chief Executive Officer, pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities and Exchange Act of 1934 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended June 30, 2019. |
| Exhibit 31.2 | Certification by Adam Logal, Chief Financial Officer, pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities and Exchange Act of 1934 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended June 30, 2019. |
| Exhibit 32.1 | Certification by Phillip Frost, Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended June 30, 2019. |
| Exhibit 32.2 | Certification by Adam Logal, Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended June 30, 2019. |
| Exhibit 101.INS | XBRL Instance Document |
| Exhibit 101.SCH | XBRL Taxonomy Extension Schema Document |
| Exhibit 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document |
| Exhibit 101.DEF | XBRL Taxonomy Extension Definition Linkbase Document |
| Exhibit 101.LAB | XBRL Taxonomy Extension Label Linkbase Document |
| Exhibit 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document |

⁽¹⁾ Filed with the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 21, 2019 and incorporated herein by reference.

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.

Date: August 7, 2019

OPKO Health, Inc.

/s/ Adam Logal

Adam Logal

Senior Vice President, Chief Financial Officer,

Chief Accounting Officer and Treasurer

CERTIFICATIONS

I, Phillip Frost, certify that:

- (1) I have reviewed this Quarterly Report on Form 10-Q of OPKO Health, Inc.;
- (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- (3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- (4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- (5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) ~~All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and~~

Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant Section 906 of the Sarbanes-Oxley Act of 2002, I, Phillip Frost, Chief Executive Officer of OPKO Health, Inc. (the "Company"), hereby certify that:

The Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2019 (the "Form 10-Q") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.
