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 Exchange Act): ¨ YES ý NO

As of November 1, 2018, the registrant had 559,827,515 shares of Common Stock outstanding.

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- failure to maintain the security of patient-related information;
- our ability to obtain and maintain intellectual property protection for our products;
- our ability to defend our intellectual property rights with respect to our products;
- our ability to operate our business without infringing the intellectual property rights of others;
- our ability to attract and retain key scientific and management personnel;
- failure to obtain and maintain regulatory approval outside the U.S.;
- legal, economic, political, regulatory, currency exchange, and other risks associated with international operations; and
- our ability to finance and successfully complete construction of a research, development and manufacturing center in Waterford, Ireland.

OPKO Health, Inc. and Subsidiaries
CONDENSED CONSOLIDATED STATEMENTS

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Pending accounting pronouncements.

In February 2016, the FASB issued ASU No. 2016-02, “Leases (Topic 842),” which will require 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, 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. ASU 2016-02 will be effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, with early adoption permitted. We have begun a process to identify a complete population of our leases. Such process includes reviewing various contra i }varDecra e p cl years, wi w

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NOTE 3 EARN

(In thousands)	September 30, 2018	December 31, 2017
Other long-term liabilities:		
Contract liabilities	$ 28,113	$ 78,990
Line of credit	104,025	104,152
Contingent consideration	26,856	29,603
Mortgages and other debts payable	1,142	1,567
Capital leases long-term	6,188	7,786
Other	17,488	17,857
	$ 183,812	$ 239,955

All of the intangible assets and goodwill acquired relate to our acquisitions of principally OPKO Renal, OPKO Biologics, EirGen Pharma Limited (“EirGen”) and BioReference. We do not anticipate capitalizing the cost of product registration renewals, rather we expect to expense these costs, as incurred. Our goodwill is not tax deductible for income tax purposes in any jurisdiction we operate in.

NOTE 5 ACQUISITIONS, INVESTMENTS AND LICENSES

Investments

The following table reflects the accounting method, carrying value and underlying equity in net assets of our unconsolidated investments as of September 30, 2018:

(in thousands)

Investment type	Investment Carrying Value	Underlying Equity in Net Assets
Equity method investments	$ 17,648	$ 20,046
Variable interest entity, equity method	956	—
Equity securities	22,183	
Equity securities with no readily determinable fair value	439	
Warrants and options	1,511	
Total carrying value of investments	$ 42,737	

Equity method investments

Our equity method investments

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NOTE 7 ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS)

For the nine months ended September 30, 2018, changes in Accumulated other comprehensive income (loss), net of tax, were as follows:

(In thousands)	Foreign currency	Unrealized gain (loss) in Accumulated OCI	Total
Balance at December 31, 2017	$ (5,404)	$ 4,876	$ (528)
Other comprehensive loss before reclassifications	(7,734)	—	(7,734)
Reclassification adjustment due to adoption of ASU 2016-01	—	(4,876)	(4,876)
Net other comprehensive loss	(7,734)	(4,876)	(12,610)
Balance at September 30, 2018	$ (13,138)	$ —	$ (13,138)

NOTE 8 FAIR VALUE MEASUREMENTS

We record fair values at an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement determined based on assumptions that market participants would use in pricing an asset or liability. We utilize a valuation framework based on the inputs used to measure fair value. These tiers include: Level 1, defined as observable inputs such as quoted prices in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions.

As of September 30, 2018, we have equity securities (refer to Note 5), forward foreign currency exchange contracts for inventory purchases (refer to Note 9) and contingent consideration related to the acquisitions of CURNA, OPKO Diagnostics and OPKO Renal that are required to be measured at fair value on a recurring basis. [illegible]

NOTE 9 DERIVATIVE CONTRACTS

The following table summarizes the fair values and the presentation of our derivative assets (liabilities) in the Condensed Consolidated Balance Sheets:

(In thousands)	Balance Sheet Component	September 30, 2018	December 31, 2017
Derivative financial instruments:			
Common Stock options/warrants	Investments, net	$ 1,511	$ 3,333
Forward contracts	Unrealized gains on forward contracts are recorded in Other current assets and prepaid expenses. Unrealized (losses) on forward contracts are recorded in Accrued expenses.	$ 23	$ (317)

We enter into foreign currency forward exchange contracts to cover the risk of exposure to exchange rate differences arising from inventory purchases and other foreign currency transactions. Under these forward contracts, for any rate above or below the fixed rate, we receive or pay the difference between the spot rate and the fixed rate for the given amount at the settlement date.

To qualify the derivative instrument as a hedge, we are required to meet strict hedge effectiveness and contemporaneous documentation requirements.

NOTE 10 RELATED PARTY TRANSACTIONS

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 include an affiliate of Dr. Phillip Frost, M.D., our Chairman and Chief Executive Officer, and Dr. Jane H. Hsiao, Ph.D., MBA, our Vice-Chairman and Chief Technical Officer.

We hold investments in Zebra (ownership 29%), Neovasc (6%), ChromaDex Corporation (0.1%), MabVax (2%), COCP (9%), NIMS (1%) 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, and in August 2016, we invested an additional $2.0 million in COCP for 162,602 shares of its common stock.

In November 2017, we invested an additional $3.0 million in Neovasc for 2,054,794 shares of its common stock, 2,054,794 Series A warrants, 2,054,794 Series B warrants and 822,192 Series C warrants. In April 2018, we exercised our Series B warrants in a cashless exercise and received 106,909,044 shares of Neovasc common stock.

In July 2017, we invested an additional $0.1 million in MabVax for 50,714 shares of common stock and in May 2017, we invested an additional $0.5 million in MabVax for 1,667 shares of Series L Preferred Stock and 107,607 shares of Series I Preferred 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. Pfenniger serve on the Board of Trustees of the Frost Science Museum and Mr. Pfenniger 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, 2017, we entered into an amendment to our lease agreement with Frost Holdings. The lease, as amended, is for approximately 29,500 square feet of space. The lease provides for payments of approximately $81 thousand per month in the first year increasing annually to $86 thousand per month in the third year, plus applicable sales tax. The rent is inclusive of operating expenses, property taxes and parking.

Our wholly-owned subsidiary, BioReference, purchases and uses certain products acquired from InCellDx, Inc., a company in which we

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NOTE 11 COMMITMENTS AND

of our contractual arrangements. Adjustments to the allowances, based on actual receipts from the third-party payers, are recorded upon settlement.

Government Payers. Reimbursements from government payers are based on fee-for-service schedules set by governmental authorities, including traditional Medicare and Medicaid. Revenues consist of amounts billed, net of contractual allowances for differences between amounts billed and the estimated consideration we expect to receive from such payers, which considers historical denial and collection experience and the terms of our contractual arrangements. Adjustments to the allowances, based on actual receipts from the government payers, are recorded upon settlement.

Client Payers. Client payers include physicians, hospitals, employers, and other institutions for which services are performed on a wholesale basis, and are billed and recognized as revenue based on negotiated fee schedules.

Patients. Uninsured patients are billed based on established patient fee schedules or fees negotiated with physicians on behalf of their patients. Insured patients (including amounts for coinsurance and deductible responsibilities) are billed based on fees negotiated with healthcare insurers. Collection of billings from patients is subject to credit risk and ability of the patients to pay. Revenues consist of amounts billed net of discounts provided to uninsured patients in accordance with our policies and implicit price concessions. Implicit price concessions represent differences between amounts billed and the estimated consideration that we expect to receive from patients, which considers historical collection experience and other factors including current market conditions. Adjustments to the estimated allowances, based on actual receipts from the patients, are recorded upon settlement.

The complexities and ambiguities of billing, reimbursement regulations and claims processing, as well as issues unique to Medicare and Medicaid programs, require us to estimate the potential for retroactive adjustments as an element of variable consideration in the recognition of revenue in the period the related services are rendered. Actual amounts are adjusted in the period those adjustments become known. For the nine months ended September 30, 2018 and 2017, revenue reductions due to changes in estimates of implicit price concessions for performance obligations satisfied in prior periods of $23.4 million and $30.7 million, respectively, were recognized.

Third-party payers, including government programs, may decide to deny payment or recoup payments for testing they contend were improperly billed or not medically necessary, against their coverage determinations, or for which they believe they have otherwise overpaid (including as a result of their own error), and we may be required to refund payments already received. Our revenues may be subject to retroactive adjustment as a result of these factors among others, including without limitation, differing interpretations of billing and coding guidance and changes by government agencies and payors in interpretations, requirements, and “conditions of participation” in various programs. We have processed requests for recoupment from third-party payers in the ordinary course of our business, and it is likely that we will continue to do so in the future. If a third-party payer denies payment for testing or recoups money from us in a later period, reimbursement revenue for our testing could decline.

As an integral part of our billing compliance program, we periodically assess our billing and coding practices, respond to payor audits on a routine basis, and investigate reported failures or suspected failures to comply with federal and state healthcare reimbursement requirements, as well as overpayment claims which may arise from time to time without fault on the part of the Company. We may have an obligation to reimburse Medicare, Medicaid, and third-party payers for overpayments regardless of fault. We have periodically identified and reported overpayments, reimbursed payors for overpayments and taken appropriate corrective action.

Settlements with third-party payors for retroactive adjustments due to audits, reviews or investigations are also considered variable consideration and are included in the determination of the estimated transaction price for providing services. These settlements are estimated based on the terms of the payment agreement with the payor, correspondence from the payor and our historical settlement activity, including an assessment of the probability a significant reversal of cumulative revenue recognized will occur when the uncertainty is subsequently resolved. Estimated settlements are adjusted in future periods as adjustments become known (that is, new information becomes available), or as years are settled or are no longer subject to such audits, review s review

and/or development activities; and royalties on sales of licensed products. Revenue is recognized upon satisfaction of a performance obligation by transferring control of a good or service to the customer.

For research, development and/or commercialization agreements that result in revenues, we identify all material performance obligations, which may include a license to intellectual property and know-how, and research and development activities. In order to determine the transaction price, in addition to any upfront payment, we estimate the amount of variable consideration at the outset of the contract either utilizing the expected value or most likely amount method, depending on the facts and circumstances relative to the contract. We constrain (reduce) our estimates of variable consideration such that it is probable that a significant reversal of previously recognized revenue will not occur throughout the life of the contract. When determining if variable consideration should be constrained, we consider whether there are factors outside of our control that could result in a significant reversal of revenue. In making these assessments, we consider the likelihood and magnitude of a potential reversal of revenue. These estimates are re-assessed each reporting period as required.

Upfront License Fees: If a license to our intellectual property is determined to be functional intellectual property distinct from the other performance obligations identified in the arrangement, we recognize revenue from nonrefundable, upfront license fees based on the relative value prescribed to the license compared to the total value of the arrangement. The revenue is recognized when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are not distinct from other obligations identified in the arrangement, we utilize 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. If the combined performance obligation is satisfied over time, we apply an appropriate method of measuring progress for purposes of recognizing revenue from nonrefundable, upfront license fees. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Development and Regulatory Milestone Payments: Depending on facts and circumstances, we may conclude that it is appropriate to include the milestone in the estimated transaction price or that it is appropriate to fully constrain the milestone. A milestone payment is included in the transaction price in the reporting period that we conclude that it is probable that recording revenue in the period will not result in a significant reversal in amounts recognized in future periods. We may record revenues from certain milestones in a reporting period before the milestone is achieved if we conclude that achievement of the milestone is probable and that recognition of revenue related to the milestone will not result in a significant reversal in amounts recognized in future periods. We record a corresponding contract asset when this conclusion is reached. Milestone payments that have been fully constrained are not included in the transaction price to date. These milestones remain fully constrained until we conclude that achievement of the milestone is probable and that recognition of revenue related to the milestone will not result in a significant reversal in amounts recognized in future periods. We re-evaluate the probability of achievement of such development milestones and any related constraint each reporting period. We adjust our estimate of the overall transaction price, including the amount of revenue recorded, if necessary.

Research and Development Activities: If we are entitled to reimbursement from our customers for specified research and development expenses, we account for them as separate performance obligations if distinct. We also determine whether the research and development funding would result in revenues or an offset to research and development expenses in accordance with provisions of gross or net revenue presentation. The corresponding revenues or offset to research and development expenses are recognized as the related performance obligations are satisfied.

Sales-based Milestone and Royalty Payments: Our customers may be required to pay us sales-based milestone payments or royalties on future sales of commercial products. We recognize revenues related to sales-based milestone and royalty payments upon the later to occur of (i) achievement of the customer's underlying sales or (ii) satisfaction of any performance obligation(s) related to these sales, in each case assuming the license to our intellectual property is deemed to be the predominant item to which the sales-based milestones and/or royalties relate.

Other Potential Products and Services: Arrangements may include an option for license rights, future supply of drug substance or drug product for either clinical development or commercial supply at the licensee's election. We assess if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations at the inception of the contract and revenue is recognized only if the option is exercised and products or services are subsequently delivered or when the rforma if sand sup $ s Pay

million and $54.2 million of revenue, respectively related to the Pfizer Transaction. Refer to Note 13. Total contract liabilities included in Accrued expenses and Other long-term liabilities was $89.8 million and $140.4 million at September 30, 2018 and December 31, 2017, respectively. The contract liability balance at September 30, 2018 relates primarily to the Pfizer Transaction.

NOTE 13 STRATEGIC ALLIANCES

Japan Tobacco Inc.

On October 12, 2017, EirGen, our wholly-owned subsidiary, and Japan Tobacco Inc. ("JT") entered into a Development and License Agreement (the "JT Agreement") granting JT the exclusive rights for the development and commercialization of *Rayaldee* in Japan (the "JT Territory"). The license grant to JT covers the therapeutic and preventative use of the product for (i) SHPT in non-dialysis and dialysis patients with CKD, (ii) rickets, and (iii) osteomalacia (the "JT Initial Indications"), as well as such additional indications as may be added to the scope of the license subject to the terms of the JT Agreement (the "JT Additional Indications" and together with the JT Initial Indications, the "JT Field").

In connection with the license, OPKO received an initial upfront payment of $6 million and received another $6 million upon the initiation of OPKO's Phase 2 study for *Rayaldee* in dialysis patients in the U.S. in September 2018. OPKO is also eligible to receive up to an additional aggregate amount of $31 million upon the achievement of certain regulatory and development milestones by JT for *Rayaldee* in the JT Territory, and $55 million upon the achievement of certain sales based milestones by JT in the JT Territory. OPKO will also receive tiered, double digit royalty payments at rates ranging from low double digits to mid-teens on net sales of *Rayaldee* within the JT Territory. JT will, at its sole cost and expense, be responsible for performing all development activities necessary to obtain all regulatory approvals for *Rayaldee* in Japan and for all commercial activities pertaining to *Rayaldee* in Japan.

The JT Agreement provides for the following: (1) an exclusive license in the JT Territory in the JT Field for the development and commercialization of *Rayaldee*; and (2) at JT's option, EirGen will supply products to support the development, sale and commercialization of the products to JT in the JT Territory.

The initial consideration primarily includes the non-refundable $6 million upfront payment and the $6 million we received upon the initiation of our Phase 2 study for *Rayaldee* in dialysis patients in the U.S. The initial consideration will be recoSa

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We manage our operations in two reportable segments, pharmaceutical and diagnostics. The pharmaceutical segment consists of our pharmaceutical operations we acquired in Chile, Mexico, Ireland, Israel and Spain, *Rayaldee* product sales and our pharmaceutical research and development. The diagnostics segment primarily consists of our clinical laboratory operations we acquired through the acquisition of BioReference and our point-of-care operations. There are no significant inter-segment sales. We evaluate the performance of each segment based on operating profit or loss. There is no inter-segment allocation of interest expense and income taxes.

(In thousands)	September 30, 2018	December 31, 2017
Assets:		
Pharmaceutical	$ 1,257,043	$ 1,287,964
Diagnostics	1,176,798	1,241,388
Corporate	47,153	60,604
	$ 2,480,994	$ 2,589,956
Goodwill:		
Pharmaceutical	$ 260,842	$ 264,313
Diagnostics	452,787	452,786
Corporate	—	—
	$ 713,629	$ 717,099

No customer represented more than 10% of our total consolidated revenue during the three d e dêl

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

OVERVIEW

You should read this discussion together with the unaudited Condensed Consolidated Financial Statements, related Notes, and other financial information included elsewhere in this report and in our Annual Report on Form 10-K for the year ended December 31, 2017 (the "Form 10-K"). The following discussion contains assumptions, estimates and other forward-looking statements that involve a number of risks and uncertainties, including those discussed under "Risk Factors," in Part II, Item 1A of

RESULTS OF OPERATIONS

FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2018 AND 2017

Effective January 1, 2018, we adopted Accounting Standards Codification Topic 606, Revenue from *Contracts with Customers*, using the full retrospective transition method. Under this method, we have revised our Condensed Consolidated Financial Statements for the years ended December 31, 2017 and 2016, and applicable interim periods within those years, as if Topic 606 had been effective for those periods. For further discussion on the impact of adopting Topic 606, refer to Note 2 to the Condensed Consolidated Financial Statements.

Revenues

(In thousands)	For the three months ended September 30, 2018	2017	Change
Revenue from services	$ 202,811	$ 200,876	$ 1,935
Revenue from products	25,395	22,795	2,600
Revenue from transfer of intellectual property and other	21,609	22,369	(760)
Total revenues	$ 249,815	$ 246,040	$ 3,775

Revenue from services for the three months ended September 30, 2018 were negatively affected by $3.5 million as a result of reduction in test volumes, reduced reimbursement of $3.9 million for clinical testing due to the Protecting Access to Medicare Act of 2014 (“PAMA”), which came into effect in January 2018, reduced genomics reimbursement of $8.4 million and payor accruals of $2.0 million of amounts previously paid. Partially offsetting these decreases, Revenue from services increased by $8.4 million from improved collections for our clinical testing.

Estimated collection amounts are subject to the complexities and ambiguities of billing, reimbursement regulations and claims processing, as well as issues unique to Medicare and Medicaid programs, and require us to consider the potential for retroactive adjustments when estimating variable consideration in the recognition of revenue in the period the related services are rendered. Actual amounts are adjusted in the period those adjustments become known based on actual collection experience. For the three months ended September 30, 2018 and 2017, changes to estimated collection amounts from third-party payors negatively affected revenue by $10.0 million and $21.4 million, respectively. The adjustments for the three months ended September 30, 2018 relate to both our clinical and genomics testing as a result of changes to payor medical and procedural requirements. The adjustments for the three months ended September 30, 2017 relate to payor claims processing adjustments due to changes to payor medical requirements for our clinical testing and delays in the billing cycle resulting from our implementation of a new clinical testing billing system in late 2016.

We may have an obligation to reimburse Medicare, Medicaid, and third-party payers for overpayments regardless of fault. We have periodically identified and reported overpayments, reimbursed payors for overpayments and taken appropriate corrective action. Settlements with third-party payors for retroactive adjustments due to audits, reviews or investigations are considered variable consideration and are included in the determination of the estimated transaction price for providing services. These settlements are estimated based on the terms of the payment agreement with the payor, correspondence from the payor and our historical settlement activity, including an assessment of the probability a significant reversal of cumulative revenue recognized will occur when the uncertainty is subsequently resolved. Estimated settlements are adjusted in future periods as adjustments become known (that is, new information becomes available), or as years are settled or are no longer subject to such audits, reviews, and investigations. During the fourth quarter of 2017, a payor informed us it had overpaid BioReference due to an error on its part over several years period, including multiple years prior to the acquisition of BioReference by OPKO in August 2015. As of September 30, 2018 and December 31, 2017, we have liabilities of approximately $32.5 million and $30.0 million within Accrued expenses related to reimbursements for payor overpayments.

The composition of Revenue from services by payor for the three months ended September 30, 2018 and 2017 is as follows:

	December 31, 2017 (in thousands)		
	As adjusted under Topic 606	As originally reported	Effect of change
Other current assets and prepaid expenses	$ 42,513	$ 37,113	$ 5,400
Accrued expenses	230,301	215,102	15,199
Other long-term liabilities, principally contract liabilities, contingent consideration and line of credit	239,955	219,954	20,001
Accumulated deficit	(1,036,959)	(1,007,159)	(29,800)

Condensed Consolidated Statement of Cash Flows

	For the nine months ended September 30, 2017 (in thousands)		
	As adjusted under Topic 606	As originally reported	Effect of change
Net loss	$ (87,336)	$ (94,965)	$ 7,629
Contract liabilities	(49,771)	(42,142)	(7,629)

The most significant change above relates to amounts in our clinical laboratory operations that were historically classified as provision for bad debts, primarily related to patient responsibility, which are considered an element of variable consideration as an implicit price concession in determining revenues under Topic 606. Accordingly, we report uncollectible balances associated with individual patients as a reduction of the transaction price and therefore as a reduction in Revenue from services when historically these amounts were classified as provision for bad debts within Selling, general and administrative expenses.

In addition, under Topic 606, the upfront consideration received for a license and contract services combined performance obligation is recognized as revenue to the extent of costs incurred based on the length of the expected performance period and the subjectivity in estimating progress towards satisfaction of the performance obligation. Under previous accounting, we recognized revenue over the expected performance period. The adoption of Topic 606 resulted in a cumulative revenue reduction of $29.8 million and an increase of our accumulated deficit balance as of December 31, 2017; with a corresponding increase in our contract liabilities. For the nine months ended September 30, 2017, Revenue from the transfer of intellectual property and other was increased by $7.6 million for the change in accounting. For a further discussion of the adoption of Topic 606, refer to Note 12, “Revenue Recognition.”

In January 2016, the FASB issued ASU No. 2016-01, “Financial Instruments - Overall (Subtopic 825-10),” which addresses certain aspects of recognition, measurement, presentation, and disclosure of financial instruments. The ASU requires equity investments (except those accounted for under the equity method of accounting or those that result in consolidation of the investee) to be measured at fair value with changes in fair value recognized in net income. As a result of the required adoption of ASU 2016-01 on January 1, 2018, we recorded a cumulative-effect adjustment to reclassifI ee unRulative-

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, 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. ASU 2016-02 will be effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, with early adoption permitted. We are currently evaluating the impact of this new guidance on our Condensed Consolidated Financial Statements. In July 2018, the FASB issued an ASU to provide an additional transition method to adopt the guidance by allowing entities to initially apply the new leases standard at the adoption date and recognize a cumulative effect to the opening balance of retained earnings.

In January 2017, the FASB issued ASU No. 2017-04, “Intangibles - Goodwill and Other (Topic 350),” which simplifies how an entity is required to test for goodwill impairment. ASU 2017-04 will be effective for annual or interim goodwill impairment tests in fiscal years beginning after December 15, 2019, with early adoption permitted after January 1, 2017. We are currently evaluating the impact of this new guidance on our Consolidated Financial Statements.

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 nonemployees. ASU 2018-07 will be effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year, with early adoption permitted. We are currently evaluating the impact of this new guidance on our Condensed Consolidated Financial Statements.

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Item 3. Quantitative and Qualitative Disclosures About Market Risk

In the normal course of doing business, we are exposed to the risks associated with foreign cur

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

We are, from time to time, party to various legal proceedings arising out of our business. During the reporting period, except as set forth below, there have been no material changes to the description of legal proceedings set forth in our Annual Report on Form 10-K for the year ended December 31, 2017.

On September 7, 2018, the Securities and Exchange Commission ("SEC") filed a lawsuit in the Southern District of New York (the "SEC Complaint") against a number of individuals and entities (the "Defendants"), including the Company and its CEO and Chairman, Phillip Frost. The SEC alleges that the Company (i) aided and abetted an illegal "pump and dump" scheme perpetrated by a number of the Defendants, and (ii) failed to file required Schedules 13D or 13G with the SEC. The Complaint also alleges that Dr. Frost participated in the alleged "pump and dump" scheme with respect to two companies, failed to file required Schedules 13D or 13G with the SEC, and unlawfully sold securities without registering the sales with the SEC. The SEC seeks final judgments permanently enjoining the Company and Dr. Frost from future violations of the charged provisions of the federal securities laws with respect to both OPKO and Dr. Frost, Sections 13(d) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 13d-1(a) thereunder relating to the alleged failure to make the appropriate filings on Schedules 13D or 13G,Section 20(e) of the Exchange Act and Section 15(b) of the Securities Act of 1933 (the "Securities Act") relating to allegations that OPKO and Dr. Frost aided and abetted the alleged "pump and dump" schemes, and, with respect to Dr. Frost alone, Sections 5(a) and (c) of the Securities Act alleging that Dr. Frost failed to register certain securities transactions, and Section 10(b) of the Exchange Act and Rule 10b-5 thereunder as well as Section 17(a)(2) of the Securities Act relating to the alleged commission of fraud. The complaint makes no allegations about OPKO's financial statements or business practices.

Following the SEC's announcement of the SEC Complaint, a number of class actions and derivative suits were filed concerning the allegations in the SEC Complaint and related matters.

On or about September 12, 2018, Jason Kerznowski ("Kerznowski"), a purported stockholder, filed a putative class action lawsuit in the United States District Court for the District of New Jersey against the Company and certain of its current and former executive officers (the "Kerznowski Lawsuit"). This lawsuit was brought by Kerznowski both individually and on behalf of a putative class of the Company's stockholders, claiming that in connection with the facts and circumstances underlying the allegations in the SEC Complaint, the Company engaged in fraudulent conduct and made false and misleading statements of material fact or omitted to state material facts necessary to make the statements made not misleading. The Kerznowski Lawsuit seeks to declare the action to be a class action and certify Kerznowski as the class representative, monetary damages, including prejudgment and post judgment interest, an award of reasonable attorneys' fees, expert fees, and other costs, and such other relief as the Court may deem just and proper.

On or about September 14, 2018, Charles Steinberg ("Steinberg"), a purported stockholder, filed a putative class action lawsuit in the United States District Court for the Southern District of Florida against the Company and certain of its current and former executive officers (the "Steinberg Lawsuit"). This lawsuit was brought by Steinberg both individually and on behalf of a putative class of the Company's stockholders claiming that in connection with the facts and circumstances underlying the allegations in the SEC Complaint, the Company engaged in fraudulent conduct and made false and misleading statements of material fact or omitted to state material facts necessary to make the statements made not misleading. The Steinberg Lawsuit seeks to declare the action to be a class action, monetary damages, including prejudgment and post judgment interest, an award of reasonable attorneys' fees and expert fees and other costs, and such additional or different relief as the interests of law or equity may require.

On or about September 17, 2018, Adsport, Inc. ("Adsport"), a purported stockholder, filed a putative class action lawsuit in the United States District Court for the Southern District of New York against the Company and Dr. Frost (the "Adsport Lawsuit"). This lawsuit was brought by Adsport individually and on behalf of a putative class of the Company's stockholders, claiming that in connection with the facts and circumstances underlying the allegations in the SEC Complaint, the Company engaged in fraudulent conduct and made false and misleading statements of material fact or omitted to state material facts necessary to make the statements made not misleading. The Adsport Lawsuit seeks to declare the action to be a proper class action, monetary damages, including interest, an award of reasonable costs, and such equitable/injunctive relief as the Court may deem proper.

On or about September 21, 2018, Michael Brennan ("Brennan"), a purported stockholder, filed a putative class action lawsuit in the United States District Court for the Southern District of Florida against the Company and certain of its current and former executive officers (the "Brennan Lawsuit"). This lawsuit was brought by Brennan individually and on behalf of a putative class of the Company's stockholders, claiming that in connection with the facts and circumstances underlying the

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On or about October 31, 2018, Lisette Demetriades ("Demetriades"), a purported stockholder, filed a shareholder derivative complaint in the United States District Court for the Southern District of Florida against the Company, certain of the Company's current and former executive officers, certain current and former members of its Board of Directors, and Frost Gamma Investment Trust (the "Demetriades Lawsuit"). The Demetriades Lawsuit alleges breach of fiduciary duty against the officers and directors named therein, based on the allegations raised by the SEC in the SEC Lawsuit, and that the Company made false and misleading statements of material fact or omitted to state material facts necessary to make the statements made not misleading, and failed to maintain effective internal controls. The lawsuit seeks to declare the action a proper derivative action, monetary damages, to direct the Company to improve its internal controls and Board oversight concerning investments and self-dealing, restitution and disgorgement of profits, an award of reasonable attorneys' fees and experts' fees, and such other and further relief as the Court deems just and proper.

On or about November 7, 2018, Esther Susan Lutzker ("Lutzker"), a purported stockholder, filed a shareholder derivative complaint in the Court of Chancery of the State of Delaware against the Company as a nominal defendant and certain members of the Company's Board of Directors (the "Lutzker Lawsuit"). This lawsuit was brought by Lutzker and alleges breach of fiduciary duty against the directors named therein, based on the allegations raised by the SEC in the SEC Complaint. The Lutzker Lawsuit seeks to declare that Lutzker maintain the action on behalf of the Company, that Lutzker is a proper and adequate representative of the Company, monetary damages, appropriate equitable relief, an award of costs and disbursements, including reasonable attorneys', accountants', and experts' fees costs and expenses, and such other and further relief as the Court may deem just and proper.

The Company intends to vigorously defend itself against the class action and derivative claims. Based on the early stages of these legal proceedings, at this time, the Company is not able to reasonably estimate a possible range of loss, if any, that may result from these allegations.

Item 1A. Risk Factors

Our operations and financial results are subject to various risks and uncertainties, including those described in Part I, Item 1A, “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2017, which could adversely affect our business, financial condition, results of operations, cash flows, and the trading price of our common and capital stock. Other than as set forth below, there have been no material changes to our risk factors since our Annual Report on Form 10-K for the year ended December 31, 2017.

We will continue to require additional funding, which may not be available to us on acceptable terms, or at all.

As of September 30, 2018, we had cash and cash equivalents of approximately $43.7 million. We have not generated sustained positive cash flows sufficient to offset our operating and research and development expenses and our primary source of cash has been from the public and private placement of stock, the issuance of the 2033 Senior Notes and 2023 Convertible Notes and credit facilities available to us.

On November 6, 2018, we entered into a Common Stock Purchase Agreement with certain investors pursuant to which we agreed to sell to such investors in private placements (the “Private Placements”) an aggregate of approximately 26.5 million shares of our Common Stock (the “Shares”) at a purchase price of $3.49 per share, which was the closing bid price of our Common Stock on the NASDAQ Global Select Market (“NASDAQ”) on such date, for an aggregate purchase price of $92.5 million. The closing of the Private Placements is subject to obtaining requisite approval from NASDAQ for the listing of the Shares. In addition, 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 approximately

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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.

Date: November 9, 2018

OPKO Health, Inc.

/s/ Adam Logal

Adam Logal
Senior Vice President, Chief Financial Officer,
Chief Accounting Officer and Treasurer

Exhibit 31.1

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 ha1teynnial repc

Exhibit 31.2

CERTIFICATIONS

I, Adam Logal, 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

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2018

/s/ Adam Logal

Adam Logal
Senior Vice President, Chief Financial Officer,
Chief Accounting Officer and Treasurer

Exhibit 32.1

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 September 30, 2018 (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.

Date: November 9, 2018

/s/ Phillip Frost, M.D.
Phillip Frost, M.D.
Chief Executive Officer

Exhibit 32.2

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, Adam Logal, C‘7Z , Ad̓am L