UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): January 18, 2023

Deciphera Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	001-38219	30-1003521
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

200 Smith Street, Waltham, Massachusetts	02451
(Address of principal executive offices)	(Zip code)

Registrant's telephone number, including area code: (781) 209-6400

(Former name or former address, if changed from last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 203.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol	Name of exchange on which registered
Common Stock, $0.01 Par Value	DCPH	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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. ☐

Item 8.01 Other Information.

On January 18, 2023, Deciphera Pharmaceuticals, Inc. (the "Company") filed a preliminary prospectus supplement with the Securities and Exchange Commission under its effective shelf registration statement on Form S-3 (Registration No. 333-266523) (the "Preliminary Prospectus Supplement") in connection with a proposed registered underwritten public offering of common stock.

The Preliminary Prospectus Supplement contains information relating to recent developments concerning the Company's business and includes the following disclosure:

Recent Developments

Preliminary Unaudited Financial Update

On January 3, 2023, the Company disclosed that it had a preliminary unaudited amount of total revenue of approximately $36 million for the fourth quarter ended December 31, 2022 and approximately $134 million for the year ended December 31, 2022. QINLOCK® (ripretinib) net product revenue is estimated to be approximately $33 million, including approximately $26 million in U.S. QINLOCK net product revenue and approximately $7 million in international QINLOCK net product revenue, in addition to approximately $3 million in collaboration revenue, for the fourth quarter ended December 31, 2022. The Company's U.S. QINLOCK net product revenue increased an estimated 20% over 2022. Approximately half of that growth was due to increased demand volume with the remainder from net price growth and a lower percentage of patients receiving free drug under the Company's patient assistance program. The increased demand observed in 2022 was driven principally by an increasing average duration of therapy.

The Company also disclosed that it had a preliminary unaudited amount of cash, cash equivalents, and marketable securities of approximately $339 million as of December 31, 2022. As of December 31, 2022, the Company had 67,637,351 and 8,855,963 shares of common stock and pre-funded warrants outstanding, respectively. These amounts are preliminary and are subject to completion of financial closing procedures. As a result, these amounts may differ materially from the amounts that will be reflected in the Company's consolidated financial statements for the year ended December 31, 2022.

The preliminary financial data included in this Current Report on Form 8-K has been prepared by, and is the responsibility of, the Company's management. PricewaterhouseCoopers LLP has not audited, reviewed, examined, compiled, nor applied agreed-upon procedures with respect to the preliminary financial data. Accordingly, PricewaterhouseCoopers LLP does not express an opinion or any other form of assurance with respect thereto.

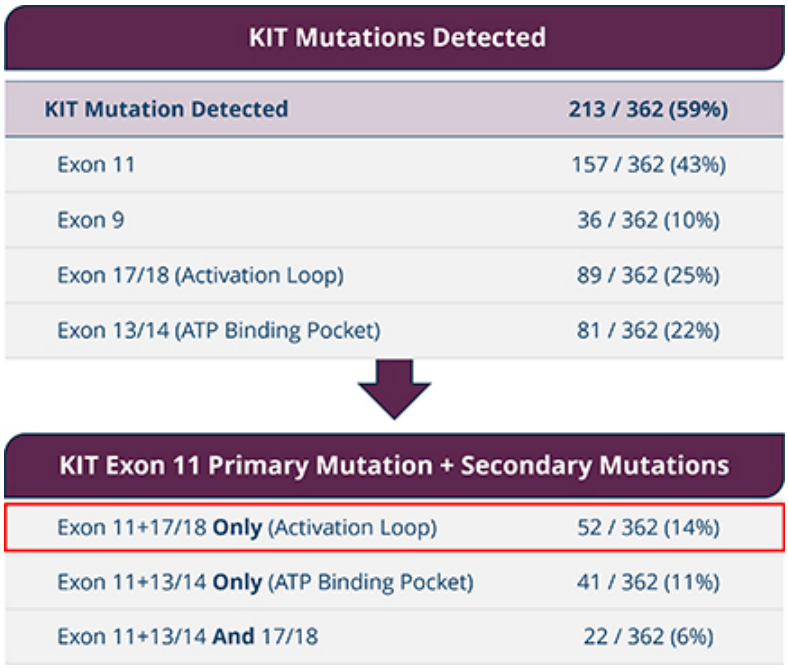
Exploratory Efficacy Analysis using ctDNA in INTRIGUE Study

Background

On January 3, 2023, the Company announced findings of an exploratory analysis using circulating tumor DNA (ctDNA) from its INTRIGUE Phase 3 clinical study of QINLOCK. The INTRIGUE Phase 3 clinical study is a randomized, global, multicenter, open-label study to evaluate the efficacy and safety of QINLOCK compared to sunitinib in patients with gastrointestinal stromal tumor (GIST) previously treated with imatinib. As previously reported, the INTRIGUE study did not achieve the primary efficacy endpoint of progression-free survival (PFS) as determined by independent radiologic review using modified Response Evaluation Criteria in Solid Tumors (mRECIST) 1.1 criteria. The statistical analysis plan included a hierarchical testing sequence that included testing patients with a KIT exon 11 primary mutation and then in the all patient intent-to-treat (AP) population. In patients with a KIT exon 11 primary mutation (n=327), QINLOCK demonstrated a mPFS of 8.3 months compared to 7.0 months for the sunitinib arm (hazard ratio [HR] 0.88, p=0.360). Although not formally tested due to the rules of the hierarchical testing sequence, in the AP population QINLOCK demonstrated a mPFS of 8.0 months compared to 8.3 months for the sunitinib arm (HR 1.05, nominal p=0.715). QINLOCK was generally well tolerated. Fewer patients in the QINLOCK arm experienced Grade 3-4 treatment-emergent adverse events compared to sunitinib (41.3% vs 65.6%).

An exploratory objective in the INTRIGUE Phase 3 study in GIST patients previously treated with imatinib was to evaluate anti-tumor efficacy of QINLOCK according to baseline KIT primary and secondary mutation status. Baseline peripheral whole blood was analyzed by Guardant360, a 74-gene ctDNA next-generation sequencing liquid biopsy assay.

Of the 453 patients in the overall intent-to-treat population (ITT), baseline ctDNA was analyzed in 362 patients for whom evaluable samples were available. ctDNA was detected in 280 samples and KIT mutations were detected in 213 patients. Primary mutations in KIT were detected in exon 11 in 157 patients and in exon 9 in 36 patients. Common resistance mutations in KIT were detected in exons 17/18 in 89 patients and in exons 13/14 in 81 patients. In patients with a KIT exon 11 primary mutation, 52 patients had mutations in exon 17/18 only, 41 patients had mutations in exon 13/14 only, and 22 patients had mutations in both exon 13/14 and exon 17/18. The figure below summarizes the KIT primary and secondary mutations that were detected in the 213 patients in which KIT mutations were detected.



Findings

Patients with mutations in KIT exon 11 and exon 17/18 only had substantially improved PFS, objective response rate (ORR), and overall survival (OS) with QINLOCK versus sunitinib. The table below summarizes these efficacy results. Efficacy results in patients with detectable ctDNA in KIT exon 11 and in the ITT populations were consistent with the primary analysis of the INTRIGUE study based on tumor data used for randomization. The subgroup safety profiles were consistent with the primary analysis.

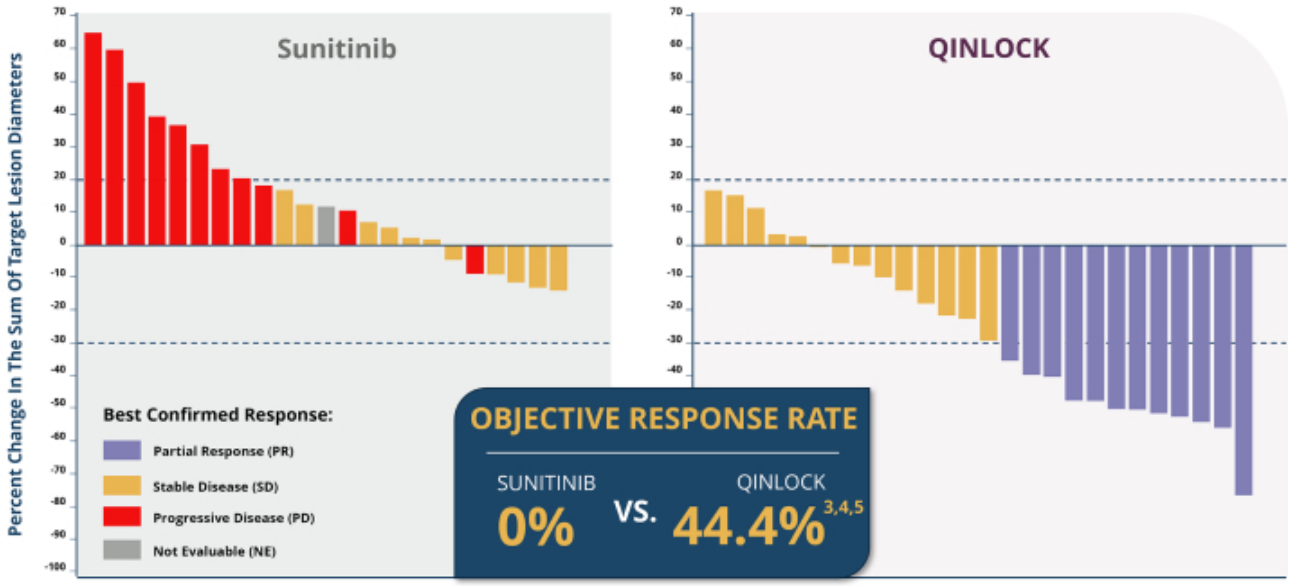
INTRIGUE Efficacy Results of ctDNA Analysis for Patients with Mutations in KIT Exon 11 and 17/18 Only

	Ripretinib (n=27)	Sunitinib (n=25)	Hazard Ratio/Response Difference (95% CI)
Median Progression-Free Survival [1]	**14.2 months**	**1.5 months**	**0.22 (0.11, 0.44),** nominal p value <0.0001
Objective Response Rate [1]	**44.4%**	**0%**	**44.4% (23.0%, 62.7%),** nominal p value = 0.0001
Overall Survival [2]	**Not Estimable**	**17.5 months**	**0.34 (0.15, 0.76),** nominal p value = 0.0061

(1) Data cut off date of September 1, 2021; (2) Data cut off date of September 1, 2022.

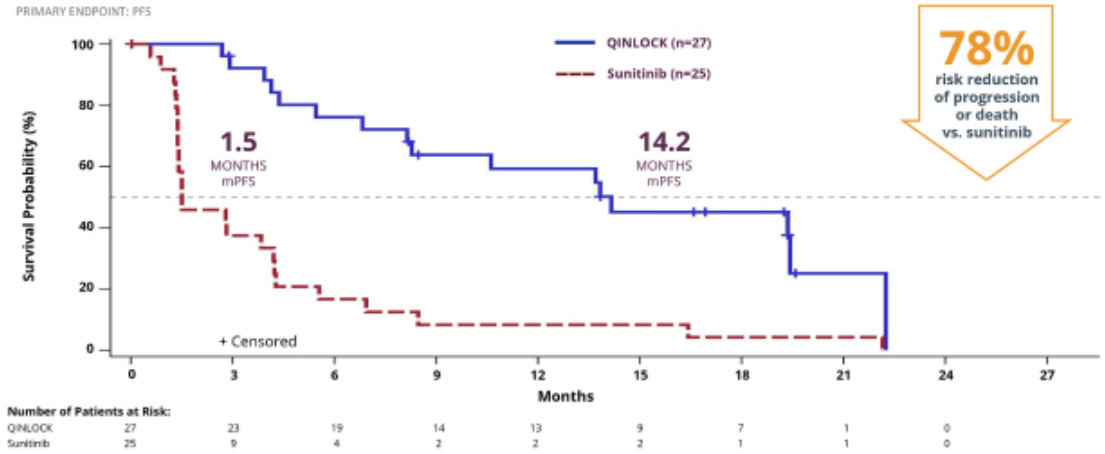
The figures below depict the ORR, PFS and OS for QINLOCK compared with sunitinib in the subgroup analysis.

Objective Response Rate for QINLOCK and sunitinib in KIT Exon 11+17/18 Only Patients[1,2]



(1) Data cut off date of September 1, 2021; (2) for 2 patients in the sunitinib arm and 1 patient in the ripretinib arm, no postbaseline disease assessment was available; (3) ORR was confirmed with follow-up imaging; (4) determined using mRECIST 1.1 criteria; (5) response difference=44.4%, 95% CI (23.0, 62.7), nominal p value 0.0001.

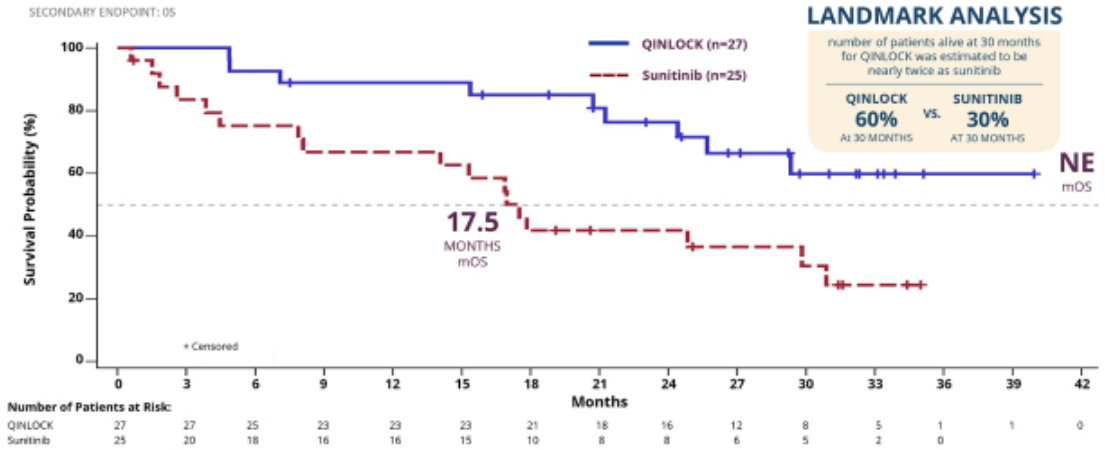
Progression Free Survival for QINLOCK and sunitinib in KIT Exon 11+17/18 Only Patients[1]



(median PFS of 14.2 months vs. 1.5 months; HR=0.22, 95% CI [0.11-0.44], nominal p value <0.0001)

(1) Data cut off date of September 1, 2021.

Overall Survival for QINLOCK and sunitinib in KIT Exon 11+17/18 Only Patients[1]



(median OS of NE months vs. 17.5 months; HR=0.34, 95% CI [0.15-0.76], nominal p value = 0.0061)

(1) Data cut off date of September 1, 2022.

Planned INSIGHT Study

Based on the results of the ctDNA analysis and discussions with the U.S. Food and Drug Administration (the FDA), the Company plans to initiate the INSIGHT pivotal Phase 3 clinical study of QINLOCK versus sunitinib in second-line GIST patients with mutations in KIT exon 11 and 17/18 only. The planned INSIGHT Phase 3 clinical study will be a randomized, global, multicenter, open-label study to evaluate the efficacy and safety of QINLOCK compared to sunitinib in patients with GIST previously treated with imatinib with mutations in KIT exon 11 and 17 and/or 18 only (excluding patients with mutations in KIT exons 9, 13, or 14). In the planned study, 54 patients will be randomized 2:1 to either QINLOCK 150 mg once daily or sunitinib 50 mg once daily for four weeks followed by two weeks without sunitinib. The primary endpoint will be PFS as determined by independent radiologic review using mRECIST 1.1 criteria. Secondary endpoints include ORR as determined by independent radiologic review using mRECIST 1.1 criteria and OS. Patients randomized to the sunitinib arm may crossover to the QINLOCK arm after progressive disease. The Company expects to initiate the INSIGHT study in the second half of 2023.

Potential U.S. Market Opportunity

As previously disclosed, the Company estimates that the annual new treatment-eligible second-line GIST patients in the U.S. are approximately 2,000. This estimate, which is based on the Company's analyses of U.S. claims data, is inherently uncertain. Based on a literature review as well as the Company's ctDNA analysis from INTRIGUE described above, the Company estimates that approximately 14% of second-line GIST patients will harbor mutations in exon 11 and exon 17/18 only.

U.S. QINLOCK net product revenue grew year-over-year based on increased demand, higher monthly price and a lower percentage of patients receiving free drug. Increased demand in 2022 compared to 2021 was driven principally by an increase in average duration of therapy to approximately 7 months, based upon the Company's estimates through the first three quarters of 2022. The Company anticipates this average duration of therapy for QINLOCK in fourth-line GIST will continue to increase modestly from approximately 7 months to approximately 8 to 8.5 months at peak. This is based upon the Company's commercial data trends, data from QINLOCK clinical trials, and published data covering a broad set of approved oncology therapeutics that compared average to median survival endpoints (e.g., PFS and OS) and demonstrated that the average commonly exceeds the median by up to 1.4 times or more. The mPFS observed in the Company's pivotal INVICTUS study for the treatment of fourth-line GIST was 6.3 months.

Second-line GIST patients receiving QINLOCK in the Company's INTRIGUE study and in the sub-group analysis described above had a mPFS greater than that observed in the Company's fourth-line GIST patients, including an mPFS of 14.2 months for the patients with mutations in KIT exon 11 and 17/18 only. The Company similarly assumes that the average duration of therapy for QINLOCK in this second-line GIST patient subpopulation will increase beyond the mPFS of 14.2 months that the Company observed. The Company estimates that INSIGHT, if successful, together with continued sales growth in fourth-line GIST has the potential to grow the Company's peak U.S. QINLOCK revenue to $350 million to $400 million per year, based on the assumptions above as well as the Company's estimates of net price growth over time, adoption of ctDNA testing for GIST patients, estimates of on-label adoption, the potential for unpromoted off-label usage and the potential impact of the Inflation Reduction Act of 2022, or the IRA, among others. Estimates are inherently uncertain and are subject to a wide variety of assumptions, risks and uncertainties that can cause actual results to differ materially.

Planned 2023 Corporate Milestones

In January 2023, the Company also announced the following planned 2023 corporate milestones:

QINLOCK® (ripretinib)

- Present additional data from the INTRIGUE Phase 3 exploratory ctDNA analysis at a medical meeting in January 2023.
- Initiate the INSIGHT pivotal Phase 3 clinical study of QINLOCK versus sunitinib in second-line GIST patients with mutations in KIT exon 11 and 17/18 only in the second half of 2023.
- Continue European geographic expansion of QINLOCK in 2023, with planned commercial launches following conclusion of pricing and reimbursement negotiations in key European markets.

Vimseltinib

- Complete enrollment for the pivotal Phase 3 MOTION study of vimseltinib, an investigational, orally administered, potent, and highly selective switch-control kinase inhibitor of CSF1R for the potential treatment of tenosynovial giant cell tumor (TGCT), in the first half of 2023 and announce top-line results from the study in the fourth quarter of 2023.
- Present updated data from the Phase 1/2 study of vimseltinib in the second half of 2023.

DCC-3116

- Present updated data from the single agent dose escalation phase and initial data from the combination dose escalation cohorts of the Phase 1/2 study of DCC-3116, an investigational switch-control kinase inhibitor of ULK1/2 designed to inhibit autophagy, in the second half of 2023.
- Initiate one or more expansion cohorts in the ongoing Phase 1/2 study of DCC-3116 in the second half of 2023 in combination with the MEK inhibitors trametinib or binimetinib, or the $KRAS^{G12C}$ inhibitor sotorasib.
- Announced a clinical trial collaboration and supply agreement with Pfizer, Inc., and plan to initiate a new dose escalation combination study evaluating DCC-3116 in combination with encorafenib and cetuximab in patients with colorectal cancer in the second half of 2023. Under the terms of the clinical trial collaboration and supply agreement with Pfizer, Inc., the Company will sponsor the trial and Pfizer will supply encorafenib at no cost.
- Present preclinical data on new clinical combinations with DCC-3116 in the first half of 2023.

DCC-3084

- Submit an investigational new drug (IND) application with the FDA for DCC-3084, a potential best-in-class pan-RAF inhibitor, in the second half of 2023.
- Present *in vitro* and *in vivo* data demonstrating a preclinical profile as a potent and selective inhibitor of BRAF/CRAF kinases, with optimized pharmaceutical properties for development in both single-agent and combination opportunities, in the first half of 2023.

Kinase Switch-Control Research Engine

- Nominate a new development candidate from the Company's proprietary discovery engine of novel switch-control inhibitors in the first half of 2023.
- Present new preclinical data from research programs at medical meetings in 2023.

Termination of ATM Prospectus

On January 18, 2023, in connection with commencing this offering, the Company delivered written notice to Jefferies LLC, or the Agent, that the Company was suspending and terminating the prospectus related to the Company's common stock, or the ATM Prospectus, issuable pursuant to the terms of the Open Market Sale Agreement℠, dated August 10, 2022, or the Open Market Sales Agreement, by and between us and the Agent. As a result, the Company will not make any sales of the Company's securities pursuant to the Open Market Sales Agreement, unless and until a new prospectus, prospectus supplement or a new registration statement is filed. Other than the termination of the ATM Prospectus, the Open Market Sales Agreement remains in full force and effect.

Cautionary Note Regarding Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding the Company's preliminary unaudited total revenue for the fourth quarter and the year ended December 31, 2022 and preliminary unaudited cash, cash equivalents, and marketable securities for the year ended December 31, 2022, the Company's expectations and timing regarding its planned Phase 3 INSIGHT study of QINLOCK versus sunitinib in second-line GIST patients with mutations in KIT exon 11 and 17/18 only, the potential peak U.S. revenue for QINLOCK, and the Company's expectations regarding upcoming corporate milestones, including but not limited to planned regulatory submissions, plans related to the commercialization of QINLOCK and the timing of its clinical studies. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "seek," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Forward-looking statements are based on current expectations of management and upon what management believes to be reasonable assumptions based on information currently available to it, and are subject to risks and uncertainties. Such risks and uncertainties may cause actual results to differ materially from the expectations set forth in the forward-looking statements. Such risks and uncertainties include, but are not limited to, risks related to preliminary financial results, including the risks that the preliminary financial results reported herein reflect information available to the Company only at this time and may differ materially from actual results, including in connection with the Company's completion of financial closing procedures, as well as other risks detailed in the Company's recent filings on Forms 10-K and 10-Q with the Securities and Exchange Commission. The Company undertakes no obligation to update any forward-looking statements to reflect new information, events or circumstances, or to reflect the occurrence of unanticipated events.

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 hereunto duly authorized.

Date: January 18, 2023

DECIPHERA PHARMACEUTICALS, INC.

By: /s/ Steven L. Hoerter
Name: Steven L. Hoerter
Title: President and Chief Executive Officer